

EXHIBIT 18

(12) **United States Patent**
Kumar et al.

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(54) **DEVICE FEATURES AND DESIGN
ELEMENTS FOR LONG-TERM ADHESION**

(58) **Field of Classification Search**
CPC A61B 5/04; A61B 5/0408; A61B 5/04085;
A61B 5/04087; A61B 5/0492;
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(56) **References Cited**

U.S. PATENT DOCUMENTS

1,497,079 A 6/1924 Gullborg
2,179,922 A 11/1939 Dana
(Continued)

FOREIGN PATENT DOCUMENTS

AU 2011252998 8/2015
AU 2014209376 6/2017
(Continued)

OTHER PUBLICATIONS

US 8,750,980 B2, 06/2014, Katra et al. (withdrawn)
(Continued)

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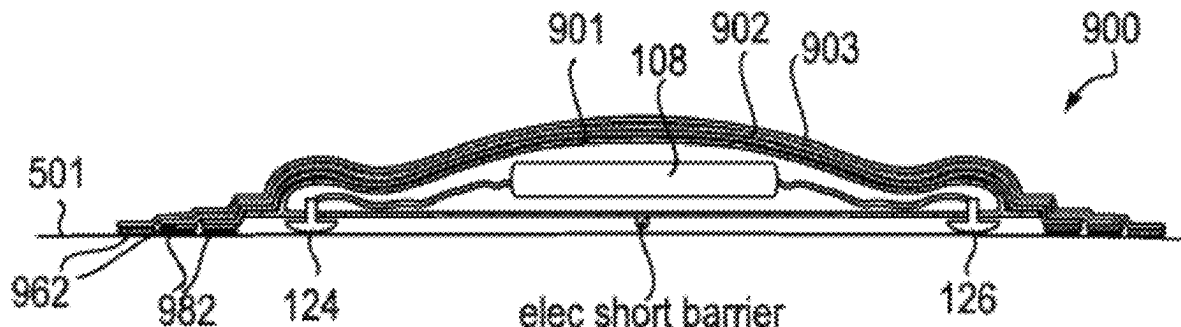
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(57) **ABSTRACT**

An electronic device for long-term adhesion to a mammal includes a housing with an electronic component. The electronic device may include a first wing and a second wing, each being integrally formed with the housing. An electrode is positioned on a bottom surface of each of the wings, the electrodes electrically connected to the electronic component. An adhesive layer is provided for adhesion to a surface of the mammal. The adhesive layer may cover a portion of the bottom surfaces of the wings but generally does not cover the electrode or a bottom surface of the housing. A method of applying an electronic device to a mammal includes removing first and second adhesive covers
(Continued)



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from first and second wings of the electronic device to expose an electrode and an adhesive coated on a bottom surface of each wing.

10 Claims, 11 Drawing Sheets

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continuation of application No. 16/723,208, filed on Dec. 20, 2019, now Pat. No. 11,141,091, which is a continuation of application No. 16/138,819, filed on Sep. 21, 2018, now Pat. No. 10,517,500, which is a continuation of application No. 15/005,854, filed on Jan. 25, 2016, now Pat. No. 10,405,799, which is a continuation of application No. 13/890,144, filed on May 8, 2013, now Pat. No. 9,241,649, which is a continuation of application No. 13/563,546, filed on Jul. 31, 2012, now Pat. No. 8,538,503, which is a continuation of application No. 13/106,750, filed on May 12, 2011, now Pat. No. 8,560,046.

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(58) Field of Classification Search

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(56)

References Cited

U.S. PATENT DOCUMENTS

2,201,645 A 5/1940 Epner
2,311,060 A 2/1943 Lurain
2,444,552 A 7/1948 Brantingson Sigurd
2,500,840 A 3/1950 Lyons
3,215,136 A 11/1965 Holter et al.
3,547,107 A 12/1970 Chapman et al.
3,697,706 A 10/1972 Huggard
3,870,034 A 3/1975 James
3,882,853 A 5/1975 Gofman
3,911,906 A 10/1975 Reinhold
4,023,312 A 5/1977 Stickney
4,027,664 A 6/1977 Heavner, Jr. et al.
4,082,087 A 4/1978 Howson
4,121,573 A 10/1978 Crovella et al.
4,123,785 A 10/1978 Cherry et al.
4,126,126 A 11/1978 Bare
4,202,139 A 5/1980 Hong et al.
4,274,419 A 6/1981 Tam et al.
4,274,420 A 6/1981 Hymes
4,286,610 A 9/1981 Jones
4,333,475 A 6/1982 Moreno et al.
4,361,990 A 12/1982 Link
4,381,792 A 5/1983 Busch

4,438,767 A 3/1984 Nelson
4,459,987 A 7/1984 Pangburn
4,535,783 A 8/1985 Marangoni
4,537,207 A 8/1985 Gilhaus
4,572,187 A 2/1986 Schettrumpf
4,621,465 A 11/1986 Pangburn
4,622,979 A 11/1986 Katchis et al.
4,623,206 A 11/1986 Fuller
4,658,826 A 4/1987 Weaver
4,712,552 A 12/1987 Pangburn
4,736,752 A 4/1988 Munck et al.
4,855,294 A 8/1989 Patel
4,925,453 A 5/1990 Kannankeril
4,938,228 A 7/1990 Righter et al.
4,981,141 A 1/1991 Segalowitz
5,003,987 A 4/1991 Grinwald
5,027,824 A 7/1991 Dougherty et al.
5,082,851 A 1/1992 Appelbaum et al.
5,086,778 A 2/1992 Mueller et al.
5,191,891 A 3/1993 Righter
5,205,295 A 4/1993 Del Mar et al.
5,226,425 A 7/1993 Righter
5,228,450 A 7/1993 Sellers
5,230,119 A 7/1993 Woods et al.
5,289,824 A 3/1994 Mills et al.
5,305,746 A 4/1994 Fendrock
5,309,909 A 5/1994 Gadsby
5,328,935 A 7/1994 Van Phan
5,365,935 A 11/1994 Righter et al.
5,458,141 A 10/1995 Neil
5,483,967 A 1/1996 Ohtake
5,489,624 A 2/1996 Kantner et al.
5,511,548 A 4/1996 Riazzi et al.
5,511,553 A 4/1996 Segalowitz
5,515,858 A 5/1996 Myllymaki
5,536,768 A 7/1996 Kantner et al.
5,581,369 A 12/1996 Righter et al.
5,626,140 A 5/1997 Feldman et al.
5,634,468 A 6/1997 Platt et al.
5,645,063 A 7/1997 Straka
5,645,068 A 7/1997 Mezack et al.
5,730,143 A 3/1998 Schwarzberg
5,749,365 A 5/1998 Magill
5,749,367 A 5/1998 Gamlyn et al.
5,771,524 A 6/1998 Woods et al.
5,772,604 A 6/1998 Langberg et al.
5,776,072 A 7/1998 Hsu et al.
5,881,743 A 3/1999 Nadel
D408,541 S 4/1999 Dunshee et al.
5,916,239 A 6/1999 Geddes et al.
5,931,791 A 8/1999 Saltzstein et al.
5,941,829 A 8/1999 Saltzstein et al.
5,957,854 A 9/1999 Besson et al.
5,959,529 A 9/1999 Kail
6,013,007 A 1/2000 Root et al.
6,032,060 A 2/2000 Carim
6,038,464 A 3/2000 Axelgaard et al.
6,038,469 A 3/2000 Karlsson et al.
6,044,515 A 4/2000 Zygmunt
6,093,146 A 7/2000 Filangeri
D429,336 S 8/2000 Francis et al.
6,102,856 A 8/2000 Groff et al.
6,117,077 A 9/2000 Del Mar et al.
6,121,508 A 9/2000 Bischof
6,132,371 A 10/2000 Dempsey et al.
6,134,480 A 10/2000 Minogue
6,136,008 A 10/2000 Becker et al.
6,161,036 A 12/2000 Matsumura et al.
6,169,915 B1 1/2001 Krumbiegel et al.
6,178,357 B1 1/2001 Gliner et al.
6,200,265 B1 3/2001 Walsh et al.
6,225,901 B1 5/2001 Kail
6,232,366 B1 5/2001 Wang et al.
6,238,338 B1 5/2001 DeLuca et al.
6,248,115 B1 6/2001 Halk
6,287,252 B1 9/2001 Lugo
6,290,707 B1 9/2001 Street
6,315,719 B1 11/2001 Rode et al.
6,379,237 B1 4/2002 Gordon

US 12,303,277 B2

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(56) **References Cited**
U.S. PATENT DOCUMENTS

6,385,473 B1	5/2002	Haines et al.	7,222,054 B2	5/2007	Geva
6,389,308 B1	5/2002	Shusterman	7,242,318 B2	7/2007	Harris
6,416,471 B1	7/2002	Kumar et al.	7,266,361 B2	9/2007	Burdett
6,453,186 B1	7/2002	Lovejoy et al.	7,316,671 B2	1/2008	Lastovich et al.
6,434,410 B1	8/2002	Cordero et al.	7,349,947 B1	3/2008	Slage et al.
6,441,747 B1	8/2002	Khair et al.	D567,949 S	4/2008	Lash et al.
6,454,708 B1	9/2002	Ferguson et al.	7,354,423 B2	4/2008	Zelickson et al.
6,456,871 B1	9/2002	Hsu et al.	7,387,607 B2	6/2008	Holt et al.
6,456,872 B1	9/2002	Faisandier	7,444,177 B2	10/2008	Nazeri
6,464,815 B1	10/2002	Beaudry	D584,414 S	1/2009	Lash et al.
6,493,898 B1	12/2002	Woods et al.	7,477,933 B2	1/2009	Ueyama
6,496,705 B1	12/2002	Ng et al.	7,478,108 B2	1/2009	Townsend et al.
6,510,339 B2	1/2003	Kovtun et al.	7,481,772 B2	1/2009	Banet
6,546,285 B1	4/2003	Owen et al.	7,482,314 B2	1/2009	Grimes et al.
6,564,090 B2	5/2003	Taha et al.	7,502,643 B2	3/2009	Farrington et al.
6,569,095 B2	5/2003	Eggers	7,539,533 B2	5/2009	Tran
6,577,893 B1	6/2003	Besson et al.	7,542,878 B2	6/2009	Nanikashvili
6,580,942 B1	6/2003	Willshire	D600,351 S	9/2009	Phillips et al.
6,585,707 B2	7/2003	Cabiri et al.	7,587,237 B2	9/2009	Korzinov et al.
6,589,170 B1	7/2003	Flach et al.	7,630,756 B2	12/2009	Linker
6,589,187 B1	7/2003	Dimberger et al.	7,632,174 B2	12/2009	Gringer et al.
6,605,046 B1	8/2003	Del Mar et al.	D607,570 S	1/2010	Phillips et al.
6,615,083 B2	9/2003	Kupper	7,672,714 B2	3/2010	Kuo et al.
6,622,035 B1	9/2003	Merilainen	7,715,905 B2	5/2010	Kurzweil et al.
6,626,865 B1	9/2003	Prisell	D618,357 S	6/2010	Navies
6,656,125 B2	12/2003	Misczynski et al.	7,729,753 B2	6/2010	Kremlovsky et al.
6,664,893 B1	12/2003	Eveland et al.	7,733,224 B2	6/2010	Tran
6,665,385 B2	12/2003	Rogers et al.	D621,048 S	8/2010	Severe et al.
6,690,959 B2	2/2004	Thompson	7,815,494 B2	10/2010	Gringer et al.
6,694,177 B2	2/2004	Eggers et al.	7,841,039 B1	11/2010	Squire
6,701,184 B2	3/2004	Henkin	7,889,070 B2	2/2011	Reeves et al.
6,711,427 B1	3/2004	Ketelhohn	7,894,888 B2	2/2011	Chan et al.
6,730,028 B2	5/2004	Eppstein	D634,431 S	3/2011	Severe et al.
D492,607 S	7/2004	Curkovic et al.	7,904,133 B2	3/2011	Gehman et al.
6,773,396 B2	8/2004	Flach et al.	7,907,956 B2	3/2011	Uhlik
6,775,566 B2	8/2004	Nissila	7,907,996 B2	3/2011	Prystowsky et al.
6,801,137 B2	10/2004	Eggers	7,941,207 B2	5/2011	Korzinov
6,801,802 B2	10/2004	Sitzman et al.	D639,437 S	6/2011	Bishay et al.
6,871,089 B2	3/2005	Korzinov et al.	7,970,450 B2	6/2011	Kroecker et al.
6,871,211 B2	3/2005	Labounty et al.	7,979,111 B2	7/2011	Acquista
6,875,174 B2	4/2005	Braun et al.	7,996,075 B2	8/2011	Korzinov et al.
6,881,191 B2	4/2005	Oakley et al.	7,996,187 B2	8/2011	Nanikashvili et al.
6,893,396 B2	5/2005	Schulze et al.	8,002,701 B2	8/2011	John et al.
6,897,788 B2	5/2005	Khair et al.	D645,968 S	9/2011	Kasabach et al.
6,904,312 B2	6/2005	Bardy	D650,911 S	12/2011	Odeh
6,925,324 B2	8/2005	Shusterman	8,077,042 B2	12/2011	Peeters
6,940,403 B2	9/2005	Kail	8,103,333 B2	1/2012	Tran
6,954,163 B2	10/2005	Toumazou et al.	8,108,036 B2	1/2012	Tran
6,957,107 B2	10/2005	Rogers et al.	8,170,639 B2	1/2012	Hauge
6,987,965 B2	1/2006	Ng et al.	8,116,841 B2	2/2012	Bly et al.
7,002,468 B2	2/2006	Eveland et al.	8,150,502 B2	4/2012	Kumar et al.
7,020,508 B2	3/2006	Stivoric et al.	8,156,945 B2	4/2012	Hart
7,024,248 B2	4/2006	Penner et al.	8,160,682 B2	4/2012	Kumar et al.
7,031,770 B2	4/2006	Collins et al.	D659,836 S	5/2012	Bensch et al.
7,072,708 B1	7/2006	Andresen et al.	8,200,319 B2	6/2012	Pu et al.
7,072,709 B2	7/2006	Xue	D663,432 S	7/2012	Nichols
7,076,283 B2	7/2006	Cho et al.	8,214,007 B2	7/2012	Baker et al.
7,076,287 B2	7/2006	Rowlandson	8,244,335 B2	8/2012	Kumar et al.
7,076,288 B2	7/2006	Skinner	8,249,686 B2	8/2012	Libbus et al.
7,076,289 B2	7/2006	Sarkar et al.	8,261,754 B2	9/2012	Pitstick
7,079,977 B2	7/2006	Osorio et al.	8,265,907 B2	9/2012	Nanikashvili et al.
7,082,327 B2	7/2006	Houben	RE43,767 E	10/2012	Eggers et al.
7,089,048 B2	8/2006	Matsumura et al.	8,280,749 B2	10/2012	Hsieh et al.
7,099,715 B2	8/2006	Korzinov et al.	8,285,356 B2	10/2012	Bly et al.
7,117,031 B2	10/2006	Lohman et al.	8,290,129 B2	10/2012	Rogers et al.
7,120,485 B2	10/2006	Glass et al.	8,290,574 B2	10/2012	Field et al.
7,130,396 B2	10/2006	Rogers et al.	8,301,219 B2	10/2012	Chen et al.
7,161,484 B2	1/2007	Tsoukalis	8,301,236 B2	10/2012	Baumann et al.
7,171,166 B2	1/2007	Ng et al.	8,311,604 B2	11/2012	Rowlandson et al.
7,179,152 B1	2/2007	Rhoades	8,315,687 B2	11/2012	Cross et al.
7,186,264 B2	3/2007	Liddicoat et al.	8,315,695 B2	11/2012	Sebelius et al.
7,193,264 B2	3/2007	Lande	8,323,188 B2	12/2012	Tran
7,194,300 B2	3/2007	Korzinov	8,326,394 B2	12/2012	Rowlandson et al.
7,206,630 B1	4/2007	Tarler	8,326,407 B2	12/2012	Linker
7,212,850 B2	5/2007	Prystowsky et al.	8,328,718 B2	12/2012	Tran
			D674,009 S	1/2013	Nichols
			8,343,116 B2	1/2013	Ignon
			8,369,936 B2	2/2013	Farrington et al.
			8,374,688 B2	2/2013	Libbus et al.

US 12,303,277 B2

Page 4

(56)

References Cited

U.S. PATENT DOCUMENTS

8,386,009 B2	2/2013	Lindberg et al.	9,044,148 B2	6/2015	Michelson et al.
8,388,543 B2	3/2013	Chon et al.	9,084,548 B2	7/2015	Bouguerra
8,406,843 B2	3/2013	Tiegs et al.	9,095,274 B2	8/2015	Fein et al.
8,412,317 B2	4/2013	Mazar	9,101,264 B2	8/2015	Acquista
8,417,326 B2	4/2013	Chon et al.	9,138,144 B2	9/2015	Geva
8,425,414 B2	4/2013	Eveland	9,149,228 B2	10/2015	Kinast
D682,437 S	5/2013	Olson et al.	9,173,670 B2	11/2015	Sepulveda et al.
8,449,471 B2	5/2013	Tran	9,179,851 B2	11/2015	Baumann et al.
8,452,356 B2	5/2013	Vestel et al.	D744,659 S	12/2015	Bishay et al.
8,460,189 B2	6/2013	Libbus et al.	9,211,076 B2	12/2015	Kim
8,473,039 B2	6/2013	Michelson et al.	9,226,679 B2	1/2016	Balda
8,473,047 B2	6/2013	Chakravarthy et al.	9,241,649 B2	1/2016	Kumar et al.
8,478,418 B2	7/2013	Fahey	9,241,650 B2	1/2016	Amirim
8,483,809 B2	7/2013	Kim et al.	9,277,864 B2	3/2016	Yang et al.
8,500,636 B2	8/2013	Tran	9,282,894 B2	3/2016	Banet et al.
8,515,529 B2	8/2013	Pu et al.	9,307,921 B2	4/2016	Friedman et al.
8,525,673 B2	9/2013	Tran	9,345,414 B1	5/2016	Bardy et al.
8,535,223 B2	9/2013	Corroy et al.	9,355,215 B2	5/2016	Vlach
8,538,503 B2	9/2013	Kumar et al.	D759,653 S	6/2016	Toth et al.
8,540,731 B2	9/2013	Kay	9,357,939 B1	6/2016	Nosrati
8,560,046 B2	10/2013	Kumar et al.	9,364,150 B2	6/2016	Sebelius et al.
8,562,527 B2	10/2013	Braun et al.	9,364,155 B2	6/2016	Bardy et al.
8,571,645 B2	10/2013	Wu et al.	9,398,853 B2	7/2016	Nanikashvili
8,588,908 B2	11/2013	Moorman et al.	9,408,545 B2	8/2016	Felix et al.
8,591,430 B2	11/2013	Amurthur et al.	9,408,551 B2	8/2016	Bardy et al.
8,591,599 B1	11/2013	Kaliki	9,408,576 B2	8/2016	Chon et al.
8,594,763 B1	11/2013	Bibian	9,414,753 B2	8/2016	Chon et al.
8,626,262 B2	1/2014	McGusty et al.	9,414,786 B1	8/2016	Brockway et al.
8,639,319 B2	1/2014	Hugh et al.	D766,447 S	9/2016	Bishay et al.
8,668,643 B2	3/2014	Kinast	9,433,367 B2	9/2016	Felix et al.
8,684,900 B2	4/2014	Tran	9,433,380 B1	9/2016	Bishay et al.
8,684,925 B2	4/2014	Amurthur et al.	9,439,566 B2	9/2016	Arne et al.
8,688,189 B2	4/2014	Shennib	9,439,599 B2	9/2016	Thompson et al.
8,688,190 B2	4/2014	Libbus et al.	9,445,719 B2	9/2016	Libbus et al.
8,688,202 B2	4/2014	Brockway et al.	9,451,890 B2	9/2016	Gitlin et al.
8,718,742 B2	5/2014	Beck et al.	9,451,975 B2	9/2016	Sepulveda et al.
8,718,752 B2	5/2014	Libbus et al.	9,474,445 B2	10/2016	Eveland
8,718,753 B2	5/2014	Chon et al.	9,474,461 B2	10/2016	Fisher et al.
8,731,632 B1	5/2014	Sereboff et al.	9,478,998 B1	10/2016	Lapetina et al.
8,738,118 B2	5/2014	Moon et al.	D773,056 S	11/2016	Vlach
8,744,561 B2	6/2014	Fahey	9,492,084 B2	11/2016	Behar et al.
8,755,876 B2	6/2014	Chon et al.	9,504,423 B1	11/2016	Bardy et al.
8,782,308 B2	7/2014	Vlach	D775,361 S	12/2016	Vosch et al.
8,789,727 B2	7/2014	Mortazavi	9,510,764 B2	12/2016	Li et al.
8,790,257 B2	7/2014	Libbus et al.	9,510,768 B2	12/2016	Rossi
8,795,174 B2	8/2014	Manicka et al.	9,526,433 B2	12/2016	Lapetina et al.
8,818,481 B2	8/2014	Bly et al.	9,545,204 B2	1/2017	Bishay et al.
8,823,490 B2	9/2014	Libbus et al.	9,545,228 B2	1/2017	Bardy et al.
8,838,218 B2	9/2014	Khair	9,554,715 B2	1/2017	Bardy et al.
8,858,450 B2	10/2014	Chon et al.	9,579,020 B2	2/2017	Libbus et al.
8,874,185 B2	10/2014	Sonnenborg	D780,914 S	3/2017	Kyvik et al.
D719,267 S	12/2014	Vaccarella	9,585,584 B2	3/2017	Marek et al.
8,903,477 B2	12/2014	Berkner	9,597,004 B2	3/2017	Hughes et al.
8,903,484 B2	12/2014	Mazar	9,615,763 B2	4/2017	Felix et al.
8,909,328 B2	12/2014	Chon	9,615,793 B2	4/2017	Solosko et al.
8,909,330 B2	12/2014	McCombie et al.	9,619,660 B1	4/2017	Felix et al.
8,909,332 B2	12/2014	Vitali et al.	9,642,537 B2	5/2017	Felix et al.
8,909,333 B2	12/2014	Rossi	9,655,518 B2	5/2017	Lin
8,909,832 B2	12/2014	Vlach et al.	9,655,537 B2	5/2017	Bardy et al.
8,926,509 B2	1/2015	Magar et al.	9,655,538 B2	5/2017	Felix
8,945,019 B2	2/2015	Prystowsky et al.	9,662,030 B2	5/2017	Thng et al.
8,948,854 B2	2/2015	Friedman et al.	9,675,264 B2	6/2017	Acquista et al.
8,954,129 B1	2/2015	Schlegel et al.	9,700,227 B2	6/2017	Bishay et al.
8,956,293 B2	2/2015	McCombie et al.	9,706,938 B2	7/2017	Chakravarthy et al.
8,968,195 B2	3/2015	Tran	9,706,956 B2	7/2017	Brockway et al.
8,972,000 B2	3/2015	Manera	9,713,428 B2	7/2017	Chon et al.
8,979,755 B2	3/2015	Szydlo-Moore et al.	D793,566 S	8/2017	Bishay et al.
9,014,777 B2	4/2015	Woo	D794,812 S	8/2017	Matsushita
9,015,008 B2	4/2015	Geva et al.	9,717,432 B2	8/2017	Bardy et al.
9,017,255 B2	4/2015	Raptis et al.	9,717,433 B2	8/2017	Felix et al.
9,017,256 B2	4/2015	Gottesman	9,730,593 B2	8/2017	Bardy et al.
9,021,161 B2	4/2015	Vlach et al.	9,730,604 B2	8/2017	Li et al.
9,021,165 B2	4/2015	Vlach	9,730,641 B2	8/2017	Felix et al.
9,026,190 B2	5/2015	Shenasa et al.	9,736,625 B1	8/2017	Landgraf et al.
9,037,223 B2	5/2015	Oral et al.	9,737,211 B2	8/2017	Bardy et al.
			9,737,224 B2	8/2017	Bardy et al.
			D797,301 S	9/2017	Chen
			D797,943 S	9/2017	Long
			D798,170 S	9/2017	Toth et al.

US 12,303,277 B2

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(56)

References Cited

U.S. PATENT DOCUMENTS

D798,294	S	9/2017	Toth et al.	10,602,977	B2	3/2020	Bardy et al.
9,775,534	B2	10/2017	Korzinov et al.	10,624,551	B2	4/2020	Bardy et al.
9,775,536	B2	10/2017	Felix et al.	10,660,520	B2	5/2020	Lin
9,782,095	B2	10/2017	Ylostalo et al.	10,667,712	B2	6/2020	Park et al.
9,782,132	B2	10/2017	Golda et al.	10,729,361	B2	8/2020	Hoppe et al.
9,788,722	B2	10/2017	Bardy et al.	10,758,139	B2	9/2020	Rapin et al.
9,801,562	B1	10/2017	Host-Madsen	10,772,521	B2	9/2020	Korzinov et al.
9,820,665	B2	11/2017	Felix et al.	10,779,744	B2	9/2020	Rapin et al.
9,839,363	B2	12/2017	Albert	10,813,565	B2	10/2020	Park et al.
D810,308	S	2/2018	Lind et al.	10,827,938	B2	11/2020	Fontanarava et al.
D811,610	S	2/2018	Abel et al.	10,866,619	B1	12/2020	Bushnell et al.
D811,611	S	2/2018	Lind et al.	10,869,610	B2	12/2020	Lu et al.
D811,615	S	2/2018	Lind et al.	10,987,018	B2	4/2021	Aga et al.
9,888,866	B2	2/2018	Chon et al.	11,004,198	B2	5/2021	Isgum et al.
9,907,478	B2	3/2018	Friedman et al.	11,017,887	B2	5/2021	Finkelmeier et al.
9,936,875	B2	4/2018	Bardy et al.	11,026,632	B2	6/2021	Narasimhan et al.
9,955,885	B2	5/2018	Felix et al.	11,051,738	B2	7/2021	Bahney et al.
9,955,887	B2	5/2018	Hughes et al.	11,051,743	B2	7/2021	Felix et al.
9,955,888	B2	5/2018	Felix et al.	11,062,804	B2	7/2021	Selvaraj et al.
9,955,911	B2	5/2018	Bardy et al.	11,083,371	B1	8/2021	Szabados et al.
9,968,274	B2	5/2018	Korzinov et al.	11,141,091	B2	10/2021	Uday et al.
9,986,921	B2	6/2018	Chon et al.	11,172,882	B2	11/2021	Upadhya et al.
10,004,415	B2	6/2018	Bishay et al.	11,246,523	B1	2/2022	Abercrombie, II et al.
D823,466	S	7/2018	Marogil	11,246,524	B2	2/2022	Szabados et al.
D824,526	S	7/2018	Ramjit et al.	11,253,185	B2	2/2022	Szabados et al.
10,045,709	B2	8/2018	Bardy et al.	11,253,186	B2	2/2022	Szabados et al.
10,052,022	B2	8/2018	Bardy et al.	11,276,491	B2	3/2022	Petterson et al.
10,076,257	B2	9/2018	Lin et al.	11,289,197	B1	3/2022	Park et al.
10,095,841	B2	10/2018	Dettinger et al.	11,324,420	B2	5/2022	Selvaraj et al.
10,098,559	B2	10/2018	Hughes et al.	11,324,441	B2	5/2022	Bardy et al.
10,111,601	B2	10/2018	Bishay et al.	11,331,034	B2	5/2022	Rapin et al.
10,123,703	B2	11/2018	Bardy et al.	11,337,632	B2	5/2022	Abercrombie, II et al.
10,154,793	B2	12/2018	Felix et al.	11,350,864	B2	7/2022	Abercrombie, II et al.
10,165,946	B2	1/2019	Bardy et al.	11,350,865	B2	7/2022	Abercrombie, II et al.
10,172,534	B2	1/2019	Felix et al.	11,375,941	B2	7/2022	Szabados et al.
10,176,575	B2	1/2019	Isgum et al.	11,382,555	B2	7/2022	Szabados et al.
10,251,575	B2	4/2019	Bardy et al.	11,399,760	B2	8/2022	Abercrombie, II et al.
10,251,576	B2	4/2019	Bardy et al.	11,445,967	B2	9/2022	Felix et al.
10,264,992	B2	4/2019	Felix et al.	11,497,432	B2	11/2022	Szabados et al.
10,265,015	B2	4/2019	Bardy et al.	11,504,041	B2	11/2022	Abercrombie, II et al.
10,270,898	B2	4/2019	Soli et al.	11,589,792	B1	2/2023	Abercrombie, II et al.
10,271,754	B2	4/2019	Bahney et al.	11,605,458	B2	3/2023	Park et al.
10,271,755	B2	4/2019	Felix et al.	11,627,902	B2	4/2023	Bahney et al.
10,271,756	B2	4/2019	Felix et al.	11,660,037	B2	5/2023	Felix et al.
10,278,603	B2	5/2019	Felix et al.	D988,518	S	6/2023	Levy et al.
10,278,606	B2	5/2019	Bishay et al.	11,678,832	B2	6/2023	Boleyn et al.
10,278,607	B2	5/2019	Prystowsky et al.	11,751,789	B2	9/2023	Abercrombie, II et al.
10,299,691	B2	5/2019	Hughes et al.	11,756,684	B2	9/2023	Park et al.
10,321,823	B2	6/2019	Chakravarthy et al.	11,806,150	B2	11/2023	Abercrombie, II et al.
10,327,657	B2	6/2019	Spencer et al.	D1,012,295	S	1/2024	Peremen et al.
D852,965	S	7/2019	Bahney et al.	11,925,469	B2	3/2024	Szabados et al.
D854,167	S	7/2019	Bahney et al.	12,133,731	B2	11/2024	Abercrombie, II et al.
10,362,467	B2	7/2019	Landgraf et al.	12,133,734	B2	11/2024	Kumar et al.
10,368,808	B2	8/2019	Lee et al.	2001/0056262	A1	12/2001	Cabiri et al.
10,376,172	B2	8/2019	Kuppuraj et al.	2002/0007126	A1	1/2002	Nissila
10,390,700	B2	8/2019	Bardy et al.	2002/0026112	A1	2/2002	Nissila et al.
10,398,344	B2	9/2019	Felix et al.	2002/0067256	A1	6/2002	Kail
10,405,799	B2	9/2019	Kumar et al.	2002/0082491	A1	6/2002	Nissila
10,413,205	B2	9/2019	Bardy et al.	2002/0087167	A1	7/2002	Winitsky
10,426,634	B1	10/2019	Al-Jazaeri et al.	2002/0180605	A1	12/2002	Ozguz et al.
10,433,743	B1	10/2019	Felix et al.	2003/0069510	A1	4/2003	Semler
10,433,748	B2	10/2019	Bishay et al.	2003/0083559	A1	5/2003	Thompson
10,433,751	B2	10/2019	Bardy et al.	2003/0125786	A1	7/2003	Gliner
10,441,184	B2	10/2019	Baummann et al.	2003/0149349	A1	8/2003	Jensen
10,463,269	B2	11/2019	Boleyn et al.	2003/0176795	A1	9/2003	Harris et al.
10,478,083	B2	11/2019	Felix et al.	2003/0195408	A1	10/2003	Hastings
10,499,812	B2	12/2019	Bardy et al.	2003/0199811	A1	10/2003	Sage, Jr. et al.
10,517,500	B2	12/2019	Kumar et al.	2003/0212319	A1	11/2003	Magill
10,555,683	B2	2/2020	Bahney et al.	2004/0032957	A1	2/2004	Mansy et al.
10,561,326	B2	2/2020	Felix et al.	2004/0068195	A1	4/2004	Massicotte et al.
10,561,328	B2	2/2020	Bishay et al.	2004/0077954	A1	4/2004	Oakley et al.
10,568,533	B2	2/2020	Soli et al.	2004/0082843	A1	4/2004	Menon
10,588,527	B2	3/2020	McNamara et al.	2004/0187297	A1	9/2004	Su
10,595,371	B2	3/2020	Gopalakrishnan et al.	2004/0199063	A1	10/2004	O'Neil
10,602,942	B2	3/2020	Shakur et al.	2004/0215091	A1	10/2004	Lohman et al.
				2004/0236202	A1	11/2004	Burton
				2004/0254587	A1	12/2004	Park
				2004/0260189	A1	12/2004	Eggers et al.
				2005/0096513	A1	5/2005	Ozguz et al.

US 12,303,277 B2

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(56)

References Cited

U.S. PATENT DOCUMENTS

2005/0101875 A1	5/2005	Semler et al.	2010/0022864 A1	1/2010	Cordero
2005/0118246 A1	6/2005	Wong et al.	2010/0042113 A1	2/2010	Mah
2005/0119580 A1	6/2005	Eveland	2010/0049006 A1	2/2010	Magar et al.
2005/0165323 A1	7/2005	Montgomery et al.	2010/0051039 A1	3/2010	Ferrara
2005/0204636 A1	9/2005	Azar et al.	2010/0056881 A1	3/2010	Libbus et al.
2005/0277841 A1	12/2005	Shennib	2010/0057056 A1	3/2010	Gurtner
2005/0280531 A1	12/2005	Fadem et al.	2010/0076533 A1	3/2010	Dar et al.
2006/0030781 A1	2/2006	Shennib	2010/0081913 A1	4/2010	Cross et al.
2006/0030782 A1	2/2006	Shennib	2010/0145359 A1	6/2010	Keller
2006/0047215 A1	3/2006	Newman et al.	2010/0191310 A1	7/2010	Bly
2006/0084883 A1	4/2006	Linker	2010/0234716 A1	9/2010	Engel
2006/0142648 A1	6/2006	Banet et al.	2010/0249625 A1	9/2010	Lin
2006/0142654 A1	6/2006	Rytty	2010/0268103 A1	10/2010	McNamara et al.
2006/0149156 A1	7/2006	Cochran et al.	2010/0312131 A1	12/2010	Naware et al.
2006/0155173 A1	7/2006	Anttila et al.	2010/0331711 A1	12/2010	Krauss et al.
2006/0155183 A1	7/2006	Kroecker et al.	2011/0021937 A1	1/2011	Hugh et al.
2006/0155199 A1	7/2006	Logier et al.	2011/0087083 A1	4/2011	Poeze et al.
2006/0155200 A1	7/2006	Ng et al.	2011/0098583 A1	4/2011	Pandia et al.
2006/0161064 A1	7/2006	Watrous et al.	2011/0119212 A1	5/2011	De Bruin et al.
2006/0161065 A1	7/2006	Elion	2011/0144470 A1	6/2011	Mazar et al.
2006/0161066 A1	7/2006	Elion	2011/0160601 A1	6/2011	Wang et al.
2006/0161067 A1	7/2006	Elion	2011/0166468 A1	7/2011	Prystowsky et al.
2006/0161068 A1	7/2006	Hastings et al.	2011/0190650 A1	8/2011	McNair
2006/0167353 A1	7/2006	Nazeri	2011/0218415 A1	9/2011	Chen
2006/0224072 A1	10/2006	Shennib	2011/0237922 A1	9/2011	Parker, III et al.
2006/0264767 A1	11/2006	Shennib	2011/0237924 A1	9/2011	McGusty et al.
2007/0003695 A1	1/2007	Tregub et al.	2011/0251504 A1	10/2011	Tereshchenko et al.
2007/0010729 A1	1/2007	Virtanen	2011/0279963 A1	11/2011	Kumar et al.
2007/0027388 A1	2/2007	Chou	2011/0306862 A1	12/2011	Hayes-Gill
2007/0088419 A1	4/2007	Florina et al.	2012/0029307 A1	2/2012	Paquet et al.
2007/0156054 A1	7/2007	Korzinov et al.	2012/0071730 A1	3/2012	Romero
2007/0208266 A1	9/2007	Hadley	2012/0071731 A1	3/2012	Gottesman
2007/0225611 A1	9/2007	Kumar et al.	2012/0071743 A1	3/2012	Todorov et al.
2007/0249946 A1	10/2007	Kumar et al.	2012/0083670 A1	4/2012	Rotondo et al.
2007/0255153 A1	11/2007	Kumar et al.	2012/0088999 A1	4/2012	Bishay et al.
2007/0270678 A1	11/2007	Fadem et al.	2012/0101396 A1	4/2012	Solosko et al.
2007/0285868 A1	12/2007	Lindberg et al.	2012/0108917 A1	5/2012	Libbus et al.
2007/0293776 A1	12/2007	Korzinov et al.	2012/0108920 A1	5/2012	Bly et al.
2007/0299325 A1	12/2007	Farrell	2012/0110226 A1	5/2012	Vlach et al.
2008/0039730 A1	2/2008	Pu et al.	2012/0110228 A1	5/2012	Vlach et al.
2008/0091089 A1	4/2008	Guillory et al.	2012/0133162 A1	5/2012	Sgobero
2008/0108890 A1	5/2008	Teng et al.	2012/0172676 A1	7/2012	Penders et al.
2008/0114232 A1	5/2008	Gazit	2012/0197150 A1	8/2012	Cao et al.
2008/0139953 A1	6/2008	Baker et al.	2012/0209102 A1	8/2012	Ylotalo et al.
2008/0167567 A1	7/2008	Bashour et al.	2012/0209126 A1	8/2012	Amos et al.
2008/0214901 A1	9/2008	Gehman et al.	2012/0215123 A1	8/2012	Kumar et al.
2008/0275327 A1	11/2008	Faarbaek et al.	2012/0220835 A1	8/2012	Chung
2008/0281215 A1	11/2008	Alhussiny	2012/0259233 A1	10/2012	Chan et al.
2008/0288026 A1	11/2008	Cross et al.	2012/0271141 A1	10/2012	Davies
2008/0309287 A1	12/2008	Reed	2012/0310070 A1	12/2012	Kumar et al.
2009/0048556 A1	2/2009	Durand	2012/0316532 A1	12/2012	McCormick
2009/0062670 A1	3/2009	Sterling et al.	2012/0323257 A1	12/2012	Sutton
2009/0062671 A1	3/2009	Brockway	2012/0330126 A1	12/2012	Hoppe et al.
2009/0073991 A1	3/2009	Landrum et al.	2013/0023816 A1	1/2013	Bachinski et al.
2009/0076336 A1	3/2009	Mazar et al.	2013/0041273 A1	2/2013	Houben et al.
2009/0076340 A1	3/2009	Libbus et al.	2013/0046151 A1	2/2013	Bsoul et al.
2009/0076341 A1	3/2009	James et al.	2013/0085347 A1	4/2013	Manicka et al.
2009/0076342 A1	3/2009	Amurthur et al.	2013/0096395 A1	4/2013	Katra et al.
2009/0076343 A1	3/2009	James et al.	2013/0116533 A1	5/2013	Lian et al.
2009/0076344 A1	3/2009	Libbus et al.	2013/0116585 A1	5/2013	Bouguerra
2009/0076345 A1	3/2009	Manicka et al.	2013/0144146 A1	6/2013	Linker
2009/0076346 A1	3/2009	James et al.	2013/0150698 A1	6/2013	Hsu et al.
2009/0076349 A1	3/2009	Libbus et al.	2013/0158494 A1	6/2013	Ong
2009/0076350 A1	3/2009	Bly et al.	2013/0172763 A1	7/2013	Wheeler
2009/0076364 A1	3/2009	Libbus et al.	2013/0184662 A1	7/2013	Aali et al.
2009/0076397 A1	3/2009	Libbus et al.	2013/0191035 A1	7/2013	Chon et al.
2009/0076401 A1	3/2009	Mazar et al.	2013/0225938 A1	8/2013	Vlach
2009/0076559 A1	3/2009	Libbus et al.	2013/0225967 A1	8/2013	Esposito
2009/0182204 A1	7/2009	Semler et al.	2013/0226018 A1	8/2013	Kumar et al.
2009/0253975 A1	10/2009	Tiegs	2013/0245415 A1	9/2013	Kumar et al.
2009/0283300 A1	11/2009	Grunthaner	2013/0245472 A1	9/2013	Eveland
2009/0292193 A1	11/2009	Wijesiriwardana	2013/0253285 A1	9/2013	Bly et al.
2009/0292194 A1	11/2009	Libbus et al.	2013/0274584 A1	10/2013	Finlay et al.
2009/0306485 A1	12/2009	Bell	2013/0296680 A1	11/2013	Linker
2010/0001541 A1	1/2010	Sugiyama	2013/0300575 A1	11/2013	Kurzweil et al.
			2013/0324868 A1	12/2013	Kaib et al.
			2013/0331663 A1	12/2013	Albert et al.
			2013/0331665 A1	12/2013	Bly et al.
			2013/0338448 A1	12/2013	Libbus et al.

US 12,303,277 B2

Page 7

(56)	References Cited		2016/0359150	A1	12/2016	de Francisco Martin et al.	
	U.S. PATENT DOCUMENTS		2016/0361015	A1	12/2016	Wang et al.	
			2016/0367164	A1	12/2016	Felix et al.	
			2016/0374583	A1	12/2016	Cerruti et al.	
2014/0012154	A1	1/2014	Mazar	2017/0042447	A1	2/2017	Rossi
2014/0058280	A1	2/2014	Cheffes et al.	2017/0055896	A1	3/2017	Al-Ali et al.
2014/0088394	A1	3/2014	Sunderland	2017/0056682	A1	3/2017	Kumar
2014/0094676	A1	4/2014	Gani et al.	2017/0065823	A1	3/2017	Kaib et al.
2014/0094709	A1	4/2014	Korzinov et al.	2017/0076641	A1	3/2017	Senanayake
2014/0100432	A1	4/2014	Golda et al.	2017/0188872	A1	7/2017	Hughes et al.
2014/0171751	A1	6/2014	Sankman et al.	2017/0188971	A1	7/2017	Hughes et al.
2014/0116825	A1	7/2014	Kurzweil et al.	2018/0049698	A1	2/2018	Berg
2014/0206976	A1	7/2014	Thompson et al.	2018/0049716	A1	2/2018	Rajagopal et al.
2014/0206977	A1	7/2014	Bahney et al.	2018/0064388	A1	3/2018	Heneghan et al.
2014/0243621	A1	8/2014	Weng et al.	2018/0110266	A1	4/2018	Lee et al.
2014/0275827	A1	9/2014	Gill et al.	2018/0125387	A1	5/2018	Hadley et al.
2014/0275840	A1	9/2014	Osorio	2018/0144241	A1	5/2018	Liu et al.
2014/0275928	A1	9/2014	Acquista et al.	2018/0146875	A1	5/2018	Friedman et al.
2014/0303647	A1	10/2014	Sepulveda et al.	2018/0161211	A1	6/2018	Beckey
2014/0330136	A1	11/2014	Manicka et al.	2018/0242876	A1	8/2018	Hughes et al.
2015/0005854	A1	1/2015	Said	2018/0257346	A1	9/2018	Austin
2015/0022372	A1	1/2015	Vosch	2018/0260706	A1	9/2018	Galloway et al.
2015/0057512	A1	2/2015	Kapoor	2018/0289274	A1	10/2018	Bahney et al.
2015/0073252	A1	3/2015	Mazar	2018/0374576	A1	12/2018	Dettinger et al.
2015/0081959	A1	3/2015	Vlach et al.	2019/0021671	A1	1/2019	Kumar et al.
2015/0082623	A1	3/2015	Felix et al.	2019/0038148	A1	2/2019	Valys
2015/0087921	A1	3/2015	Felix et al.	2019/0046066	A1	2/2019	Hughes et al.
2015/0087922	A1	3/2015	Bardy et al.	2019/0069788	A1	3/2019	Coleman et al.
2015/0087923	A1	3/2015	Bardy et al.	2019/0090769	A1	3/2019	Boleyn et al.
2015/0087933	A1	3/2015	Gibson et al.	2019/0097339	A1	3/2019	Lim et al.
2015/0087948	A1	3/2015	Bishay et al.	2019/0098758	A1	3/2019	Hassemer et al.
2015/0087949	A1	3/2015	Felix et al.	2019/0099132	A1	4/2019	Mulinti et al.
2015/0087950	A1	3/2015	Felix et al.	2019/0167143	A1	6/2019	Li et al.
2015/0087951	A1	3/2015	Felix et al.	2019/0209022	A1	7/2019	Sobol
2015/0088007	A1	3/2015	Bardy et al.	2019/0246928	A1	8/2019	Bahney et al.
2015/0088020	A1	3/2015	Dreisbach et al.	2019/0274574	A1	9/2019	Hughes et al.
2015/0094556	A1	4/2015	Geva et al.	2019/0282178	A1	9/2019	Volosin et al.
2015/0148637	A1	5/2015	Golda et al.	2019/0290147	A1	9/2019	Persen et al.
2015/0157273	A1	6/2015	An et al.	2019/0298201	A1	10/2019	Persen et al.
2015/0173671	A1	6/2015	Paalasmaa et al.	2019/0298209	A1	10/2019	Persen et al.
2015/0193595	A1	7/2015	McNamara et al.	2019/0298272	A1	10/2019	Persen
2015/0223711	A1	8/2015	Raeder et al.	2019/0374163	A1	12/2019	Faabaek et al.
2015/0238107	A1	8/2015	Acquista et al.	2019/0378617	A1	12/2019	Charles et al.
2015/0289814	A1	10/2015	Magar et al.	2020/0060563	A1	2/2020	Boleyn
2015/0297134	A1	10/2015	Albert et al.	2020/0093388	A1	3/2020	Bouguerra et al.
2015/0327781	A1	11/2015	Hernandez-Silverira et al.	2020/0100693	A1	4/2020	Velo
2015/0351689	A1	12/2015	Adams	2020/0108260	A1	4/2020	Haddad et al.
2015/0351799	A1	12/2015	Sepulveda et al.	2020/0121209	A1	4/2020	Kumar et al.
2015/0374244	A1	12/2015	Yoo et al.	2020/0170529	A1	6/2020	Bahney et al.
2016/0022161	A1	1/2016	Khair	2020/0178825	A1	6/2020	Lu
2016/0029906	A1	2/2016	Tompkins et al.	2020/0178828	A1	6/2020	Bahney et al.
2016/0066808	A1	3/2016	Hijazi	2020/0193597	A1	6/2020	Fan et al.
2016/0085927	A1	3/2016	Dettinger et al.	2020/0196897	A1	6/2020	Biswas et al.
2016/0085937	A1	3/2016	Dettinger et al.	2020/0214563	A1	7/2020	Lin
2016/0086297	A1	3/2016	Dettinger et al.	2020/0214584	A1	7/2020	McNamara et al.
2016/0098536	A1	4/2016	Dettinger et al.	2020/0237309	A1	7/2020	Golda et al.
2016/0098537	A1	4/2016	Dettinger et al.	2020/0289014	A1	9/2020	Park et al.
2016/0113520	A1	4/2016	Manera	2020/0337608	A1	10/2020	Garai et al.
2016/0120433	A1	5/2016	Hughes et al.	2020/0352489	A1	11/2020	Hoppe et al.
2016/0120434	A1	5/2016	Park et al.	2020/0367779	A1	11/2020	Korzinov et al.
2016/0128597	A1	5/2016	Lin et al.	2020/0397313	A1	12/2020	Attia et al.
2016/0135746	A1	5/2016	Kumar et al.	2021/0038102	A1	2/2021	Boleyn et al.
2016/0149292	A1	5/2016	Ganton	2021/0059612	A1	3/2021	Krebs et al.
2016/0157744	A1	6/2016	Wu et al.	2021/0085215	A1	3/2021	Auerbach et al.
2016/0166155	A1	6/2016	Banet et al.	2021/0085255	A1	3/2021	Vule et al.
2016/0192852	A1	7/2016	Bozza et al.	2021/0125722	A1	4/2021	Sherkat et al.
2016/0192855	A1	7/2016	Geva et al.	2021/0153761	A1	5/2021	Jung et al.
2016/0192856	A1	7/2016	Lee	2021/0217519	A1	7/2021	Park et al.
2016/0198972	A1	7/2016	Lee et al.	2021/0244279	A1	8/2021	Szabados et al.
2016/0232807	A1	8/2016	Ghaffari et al.	2021/0269046	A1	9/2021	Hashimoto et al.
2016/0262619	A1	9/2016	Marcus et al.	2021/0298688	A1	9/2021	Banerjee et al.
2016/0278658	A1	9/2016	Bardy et al.	2021/0304855	A1	9/2021	Ansari et al.
2016/0287177	A1	10/2016	Huppert et al.	2021/0315470	A1	10/2021	Wu et al.
2016/0287207	A1	10/2016	Xue	2021/0315504	A1	10/2021	Kumar et al.
2016/0296132	A1	10/2016	Bojovic et al.	2021/0361218	A1	11/2021	Szabados et al.
2016/0302725	A1	10/2016	Schultz et al.	2021/0369178	A1	12/2021	Szabados et al.
2016/0302726	A1	10/2016	Chang	2021/0374502	A1	12/2021	Roth et al.
2016/0317048	A1	11/2016	Chan et al.	2021/0378579	A1	12/2021	Doron et al.
2016/0317057	A1	11/2016	Li et al.	2021/0393187	A1	12/2021	Amos et al.

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Page 8

(56)	References Cited			EP	3165161	5/2017
	U.S. PATENT DOCUMENTS			EP	3212061	9/2017
				EP	3753483	12/2020
				EP	3387991	6/2022
2022/0022798	A1	1/2022	Soon-Shiong et al.	EP	4103051	12/2022
2022/0031223	A1	2/2022	Li et al.	GB	2 299 038	9/1996
2022/0039719	A1	2/2022	Abercrombie, II et al.	GB	2 348 707	10/2000
2022/0039720	A1	2/2022	Abercrombie, II et al.	IN	002592907-0001	12/2014
2022/0039721	A1	2/2022	Abercrombie, II et al.	JP	S61-137539	6/1986
2022/0039722	A1	2/2022	Abercrombie, II et al.	JP	H05-329123	12/1993
2022/0079497	A1	3/2022	Bardy et al.	JP	H08-317913	3/1996
2022/0093247	A1	3/2022	Park et al.	JP	H08-322952	12/1996
2022/0095982	A1	3/2022	de Saint Victor et al.	JP	2000-126145	5/2000
2022/0142493	A1	5/2022	Albert	JP	2001-057967	3/2001
2022/0142495	A1	5/2022	De Marco et al.	JP	2003-275186	9/2003
2022/0160279	A1	5/2022	Abercrombie, II et al.	JP	2004-121360	4/2004
2022/0160285	A1	5/2022	Szabados et al.	JP	2006-110180	4/2006
2022/0167905	A1	6/2022	Szabados et al.	JP	2006-136405	6/2006
2022/0280093	A1	9/2022	Abercrombie, II et al.	JP	2006-520657	9/2006
2022/0296144	A1	9/2022	Abercrombie, II et al.	JP	2007-045967	2/2007
2022/0330874	A1	10/2022	Szabados et al.	JP	2007-503910	3/2007
2022/0330875	A1	10/2022	Szabados et al.	JP	2007-504917	3/2007
2022/0361793	A1	11/2022	Abercrombie, II et al.	JP	2007-097822	4/2007
2023/0056777	A1	2/2023	Abercrombie, II et al.	JP	2007-296266	11/2007
2023/0172511	A1	6/2023	Abercrombie, II et al.	JP	2008-532596	8/2008
2023/0172518	A1	6/2023	Szabados et al.	JP	2008-200120	9/2008
2023/0200702	A1	6/2023	Sepulveda et al.	JP	2009-518099	5/2009
2023/0207122	A1	6/2023	Park et al.	JP	2009-525816	7/2009
2023/0248288	A1	8/2023	Bahney et al.	JP	2011-516110	5/2011
2023/0371873	A1	11/2023	Abercrombie, II et al.	JP	2011-519583	7/2011
2023/0371874	A1	11/2023	Abercrombie, II et al.	JP	2013-521966	6/2013
2024/0145080	A1	5/2024	Park et al.	JP	5203973	6/2013
2024/0321455	A1	9/2024	Hytopoulos et al.	JP	1483906 S	10/2013
2024/0331875	A1	10/2024	Hytopoulos et al.	JP	2014-008166	1/2014
2024/0382130	A1	11/2024	Bahney et al.	JP	5559425	7/2014
2024/0382131	A1	11/2024	Bahney et al.	JP	2014-150826	8/2014
2024/0398310	A1	12/2024	Kumar et al.	JP	2014-236982	12/2014
2025/0009271	A1	1/2025	Bahney et al.	JP	2015-530225	10/2015
				JP	2015-531954	11/2015
				JP	2016-504159	2/2016
				JP	2013-517053	5/2016
				JP	2016-523139	8/2016
AU	2021218704	2/2024		JP	2017-136380	8/2017
CA	2 752 154	8/2010		JP	6198849	9/2017
CA	2 898 626	7/2014		JP	2017-209482	11/2017
CA	2 797 980	8/2015		JP	2018-504148	2/2018
CA	2 651 203	9/2017		JP	2018-508325	3/2018
CA	2 966 182	6/2020		JP	2018-513702	5/2018
CA	3 171 482	3/2024		JP	6336640	5/2018
CN	102038497	7/2012		JP	D1596476	8/2018
CN	102883775	12/2014		JP	2018-153651	10/2018
CN	103997955	11/2016		JP	2018-174995	11/2018
CN	303936805	11/2016		JP	2019-503761	2/2019
CN	107205679	9/2017		JP	6491826	3/2019
CN	108113647	6/2018		JP	6495228	3/2019
CN	109363659	2/2019		JP	2019-140680	8/2019
CN	110491500	11/2019		JP	2019-528511	10/2019
CN	110766691	2/2020		JP	2020-058819	4/2020
CN	110890155	3/2020		JP	2020-509840	4/2020
CN	110974217	4/2020		JP	6766199	9/2020
CN	115426940	12/2022		JP	2021-003591	1/2021
CN	116322498	6/2023		JP	6901543	6/2021
CN	116530951	8/2023		JP	2021-525616	9/2021
EM	001857966-0001	5/2011		JP	2021-166726	10/2021
EM	003611714-0001	1/2017		JP	2022-501123	1/2022
EM	003611714-0002	1/2017		JP	2022-037153	3/2022
EM	003611714-0003	1/2017		JP	2022-038858	3/2022
EM	003611714-0004	1/2017		JP	2022-126807	8/2022
EM	003611714-0005	1/2017		JP	2023-508235	3/2023
EP	0509689	4/1992		JP	2023-074267	5/2023
EP	1738686	6/2006		JP	2023-100210	7/2023
EP	1782729	5/2007		JP	2023-536981	8/2023
EP	1981402	10/2008		JP	2023-536982	8/2023
EP	2262419	12/2010		JP	7406001	12/2023
EP	2395911	12/2011		JP	2024-009608	1/2024
EP	2568878	3/2013		JP	2024-502335	1/2024
EP	2635179	9/2013		JP	2024-021061	2/2024
EP	2635180	9/2013		JP	2024-026058	2/2024
EP	2948050	12/2015		JP	7431777	2/2024
EP	2983593	2/2016				

US 12,303,277 B2

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(56) References Cited

FOREIGN PATENT DOCUMENTS

JP	2024-050777	4/2024
JP	2024-521799	6/2024
JP	2024-087811	7/2024
JP	2024-104034	8/2024
JP	7551696	9/2024
JP	2024-164285	11/2024
JP	2025-000653	1/2025
KR	3003784570000	3/2005
KR	1020050055072	6/2005
KR	1020140050374	4/2014
KR	10-1513288	4/2015
KR	3008476060000	3/2016
KR	3008476090000	3/2016
KR	3008482960000	3/2016
KR	3008584120000	6/2016
KR	3008953750000	2/2017
KR	3008953760000	2/2017
KR	3008987790000	3/2017
KR	1020170133527	12/2017
KR	3009445870000	2/2018
KR	3009547690000	4/2018
KR	3009547710000	4/2018
KR	10-2019-0114694	10/2019
KR	10-2563372	7/2023
KR	10-2023-0119036	8/2023
WO	WO 99/023943	5/1999
WO	WO 01/016607	3/2001
WO	WO 2003/043494	5/2003
WO	WO 2004/100785	11/2004
WO	WO 2005/025668	3/2005
WO	WO 2005/037946	4/2005
WO	WO 2005/084533	9/2005
WO	WO 2006/094513	9/2006
WO	WO 2007/049080	3/2007
WO	WO 2007/036748	4/2007
WO	WO 2007/063436	6/2007
WO	WO 2007/066270	6/2007
WO	WO 2007/071180	6/2007
WO	WO 2007/072069	6/2007
WO	WO 2007/092543	8/2007
WO	WO 2008/005015	1/2008
WO	WO 2008/005016	1/2008
WO	WO 2008/057884	5/2008
WO	WO 2008/120154	10/2008
WO	WO 2009/055397	4/2009
WO	WO 2009/074928	6/2009
WO	WO 2009/112972	9/2009
WO	WO 2009/112976	9/2009
WO	WO 2009/112979	9/2009
WO	WO 2009/134826	11/2009
WO	WO 2010/014490	2/2010
WO	WO 2010/104952	9/2010
WO	WO 2010/105203	9/2010
WO	WO 2010/107913 A2	9/2010
WO	WO 2010/093900	10/2010
WO	WO 2011/077097	6/2011
WO	WO 2011/084636	7/2011
WO	WO 2011/112420	9/2011
WO	WO 2011/143490	11/2011
WO	WO 2011/149755	12/2011
WO	WO 2012/003840	1/2012
WO	WO 2012/009453	1/2012
WO	WO 2012/061509	5/2012
WO	WO 2012/061518	5/2012
WO	WO 2012/125425	9/2012
WO	WO 2012/140559	10/2012
WO	WO 2012/160550	11/2012
WO	WO 2013/065147	5/2013
WO	WO 2013/179368	12/2013
WO	WO 2014/047032	3/2014
WO	WO 2014/047205	3/2014
WO	WO 2014/051563	4/2014
WO	WO 2014/055994	4/2014
WO	WO 2014/116825	7/2014
WO	WO 2014/168841	10/2014

WO	WO 2014/197822	12/2014
WO	WO 2015/089484	6/2015
WO	WO 2016/044514	3/2016
WO	WO 2016/044515	3/2016
WO	WO 2016/044519	3/2016
WO	WO 2016/057728	4/2016
WO	WO 2016/070128	5/2016
WO	WO 2016/130545	8/2016
WO	WO 2016/172201	10/2016
WO	WO 2016/181321	11/2016
WO	WO 2017/039518	3/2017
WO	WO 2017/041014	3/2017
WO	WO 2017/043597	3/2017
WO	WO 2017/043603	3/2017
WO	WO 2017/108215	6/2017
WO	WO 2017/159635	9/2017
WO	WO 2018/164840	9/2018
WO	WO 2018/218310	12/2018
WO	WO 2019/070978	4/2019
WO	WO 2019/071201	4/2019
WO	WO 2019/188311	10/2019
WO	WO 2019/191487	10/2019
WO	WO 2019/233807	12/2019
WO	WO 2020/008864	1/2020
WO	WO 2020/013895	1/2020
WO	WO 2020/041363	2/2020
WO	WO 2020/058314	3/2020
WO	WO 2020/224041	11/2020
WO	WO 2020/0226852	11/2020
WO	WO 2020/262403	12/2020
WO	WO 2021/150122	7/2021
WO	WO 2021/163331	8/2021
WO	WO 2021/200245	10/2021
WO	WO 2021/200764	10/2021
WO	WO 2021/205788	10/2021
WO	WO 2021/210592	10/2021
WO	WO 2021/241308	12/2021
WO	WO 2021/245203	12/2021
WO	WO 2022/034045	2/2022
WO	WO 2022/093709	5/2022
WO	WO 2022/147520	7/2022
WO	WO 2022/251636	12/2022
WO	WO 2023/114742	6/2023
WO	WO 2024/102663 A2	5/2024

OTHER PUBLICATIONS

Behind the Design: How iRhythm Built Its New Zio Monitor. Online, published date Oct. 4, 2023. Retrieved on Jun. 18, 2024 from URL: <https://www.mddionline.com/cardiovascular/behind-the-design-how-irhythm-built-its-new-zio-monitor>.

3M Corporation, "3M Surgical Tapes—Choose the Correct Tape" quicksheet (2004).

Altini, et al., An ECG Patch Combining a Customized Ultra-Low-Power ECG SOC With Bluetooth Low Energy for Long Term Ambulatory Monitoring, Conference: Proceedings of Wireless Health 2011, WH 2011, Oct. 10-13, 2011.

British-Made Early Warning Monitor a "Game Changer", healthcare-in-europe.com, Mar. 31, 2014.

Comstock, Proteus Digital Health Quietly Launches Consumer-Facing Wearable for Athletes, Mobile Health News, Oct. 29, 2014.

Coxworth, Small Adhesive Patch Outperforms Traditional Tech for Detecting Arrhythmia, Scripps, iRhythm Technologies, Jan. 3, 2014.

Del Mar et al.; The history of clinical holter monitoring; A.N.E. ; vol. 10; No. 2; pp. 226-230; Apr. 2005.

Enseleit et al.; Long-term continuous external electrocardiogram: a review; Eurospace; vol. 8; pp. 255-266; 2006.

Hoefman et al.; Optimal duration of event recording for diagnosis of arrhythmias in patients with palpitations and light-headedness in the general practice; Family Practice; Dec. 7, 2006.

Huyett "Keystock & Shim Stock Catalog" p. Feb. 9, 2014. found at <https://issuu.com/glhuyett/docs/gl-huyett-keystock-catalog/20> (Year: 2014).

US 12,303,277 B2

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(56)

References Cited

OTHER PUBLICATIONS

Ikedo Y. et al., "A Method for Transmission Data Reduction for Automated Monitoring System via CNN Distribution Process", Proceedings of the Symposium of Multi-media, Distribution, Coordination, and Mobile (DOCOMO2019), Jul. 2019.
International Preliminary Report on Patentability and Written Opinion in PCT Application No. PCT/US2011/036335, dated Nov. 22, 2012.
International Search Report and Written Opinion in PCT Application No. PCT/US2011/036335, dated Oct. 31, 2011.
Kennedy et al.; The history, science, and innovation of holter technology; A.N.E.; vol. 11; No. 1; pp. 85-94; 2006.
"Mayo Alumni", Mayo Clinic, Rochester, MN, Spring 2011, in 24 pages.
Medtronic Launches SEEQ Wearable Cardiac Monitoring System in United States, Diagnostic and Interventional Cardiology, Oct. 7, 2014.
Mundt et al. "A Multiparameter Wearable Physiologic Monitoring System for Space and Terrestrial Applications" IEEE Transactions on Information Technology in Biomedicine, vol. 9, No. 3, pp. 382-384, Sep. 2005.
Prakash, New Patch-Based Wearable Sensor Combines Advanced Skin Adhesives and Sensor Technologies, Advantage Business Marketing, Jul. 17, 2012.
Redjem Bouhenguel et al., "A risk and Incidence Based Atrial Fibrillation Detection Scheme for Wearable Healthcare Computing Devices," Pervasive Computer Technologies for Healthcare, 2012 6th International Conference On, IEEE, pp. 97-104, May 21, 2012.
Reiffel et al.; Comparison of autotriggered memory loop recorders versus standard loop recorders versus 24-hour holter monitors for arrhythmia detection; Am. J. Cardiology; vol. 95; pp. 1055-1059; May 1, 2005.

Request for Reexamination of U.S. Pat. No. 7,020,508 under 35 U.S.C. §§ 311-318 and 37 C.F.R. § 1.913 as submitted Sep. 14, 2012 in 78 pages.
Scapa Medical product listing and descriptions (2008) available at <http://www.caapana.com/productlist.jsp> and <http://www.metplus.co.rs/pdf/prospekti/Samolepljivemedicinsketrake.pdf>; retrieved via WayBack Machine Sep. 24, 2012.
Strong, Wearable Technologies Conference 2013 Europe—Notes and Roundup, Wearable Technologies Conference, Feb. 8, 2013.
Sumner, Stanford Engineers Monitor Heart Health Using Paper-Thin Flexible 'Skin', Stanford Report, May 14, 2013.
Ward et al.; Assessment of the diagnostic value of 24-hour ambulatory electrocardiogram monitoring; Biotelemetry Patient monitoring; vol. 7; 1980.
Ziegler et al.; Comparison of continuous versus intermittent monitoring of atrial arrhythmias; Heart Rhythm; vol. 3; No. 12; pp. 1445-1452; Dec. 2006.
Zimetbaum et al.; The evolving role of ambulatory arrhythmia monitoring in general clinic practice; Ann. Intern. Med.; vol. 130; pp. 846-8556; 1999.
Zimetbaum et al.; Utility of patient-activated cardiac event recorders in general clinical practice; The Amer. J. of Cardiology; vol. 79; Feb. 1, 1997.
Akram, Muhammad Usman, "Application of Prototype Based Fuzzy Classifiers for ECG based Cardiac Arrhythmia Recognition", Jan. 1, 2008 retrieved from faculty.pieas.edu.pk/Fayyaz/_static/pubfiles/student/usman_thesis.pdf [retrieved on Feb. 17, 2015] in 93 pages.
Feng-Tso Sun et al., "PEAR: Power efficiency through activity recognition (for ECG-based sensing)", Pervasive Computing Technologies for Healthcare (PervasiveHealth) 2011 5th International Conference on, IEEE, May 23, 2011. pp. 115-122.
Rajpurkar et al., "Cardiologist-Level Arrhythmia Detection with Convolutional Neural Networks," Arxiv.org, <https://arxiv.org/abs/1707.01836>, Jul. 6, 2017 in 9 pages.
YouTube.com, "Demonstration of Nintendo controller repair," <https://www.youtube.com/watch?v=hzybDNChNeU>, Aug. 2010.

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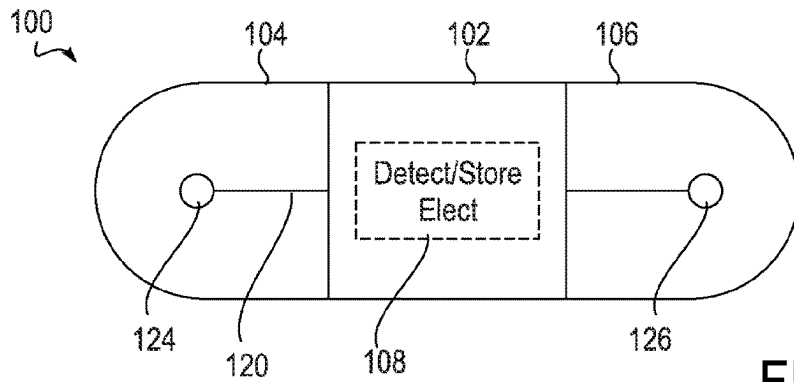


FIG. 1

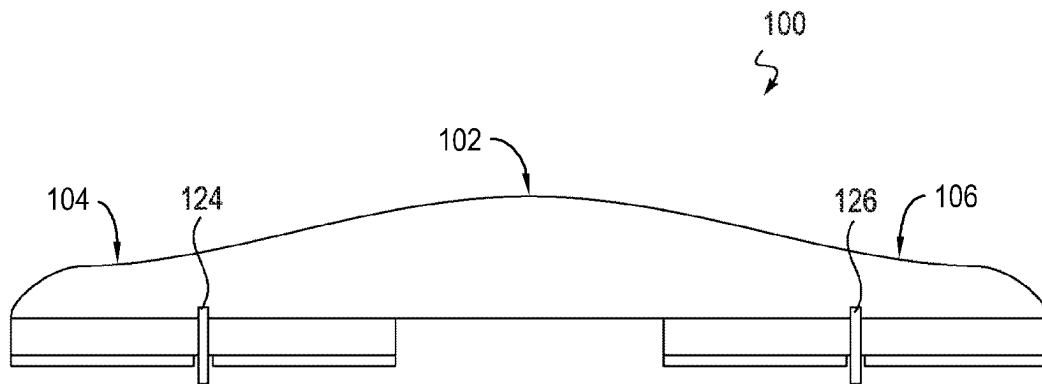


FIG. 1A

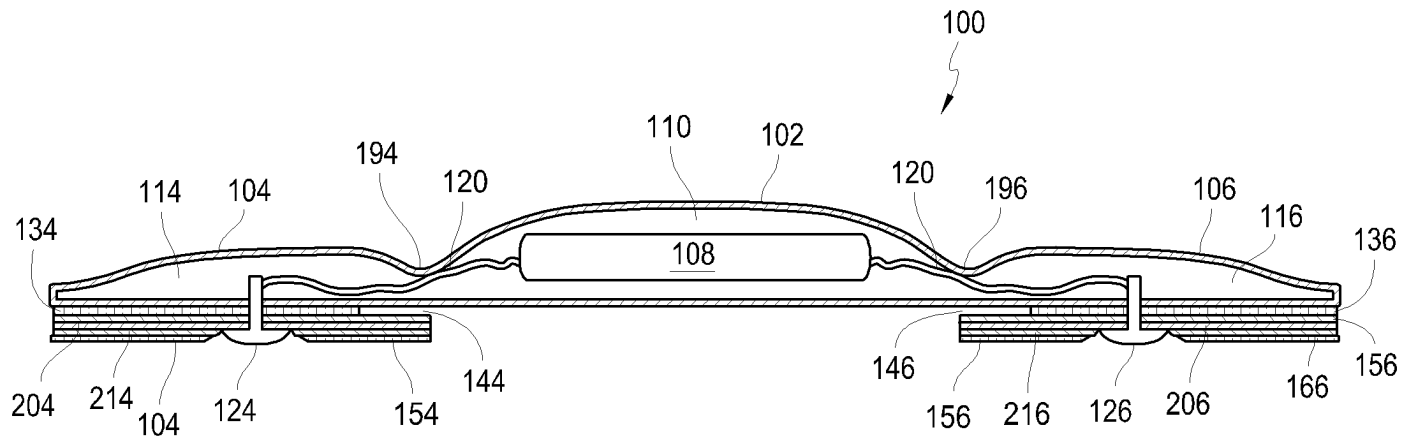


FIG. 1B

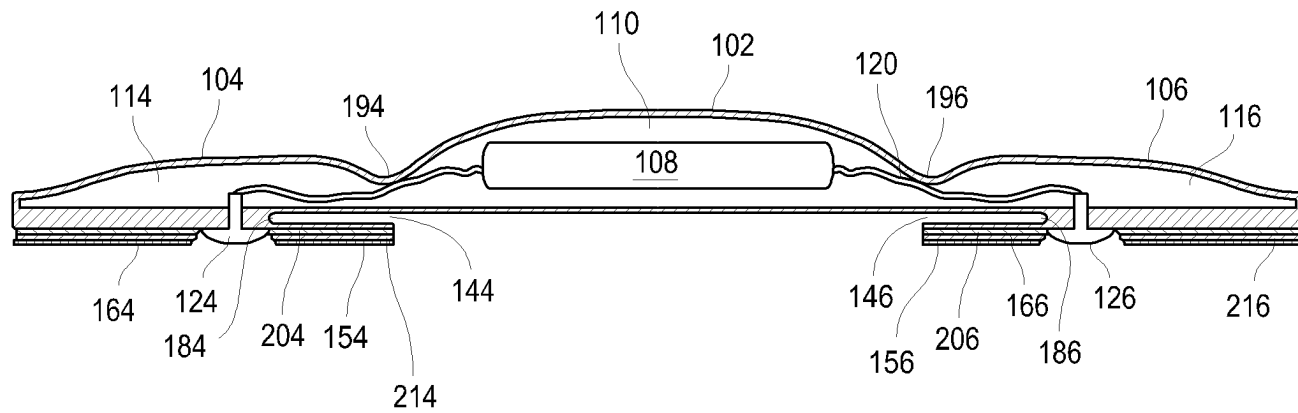


FIG. 1C

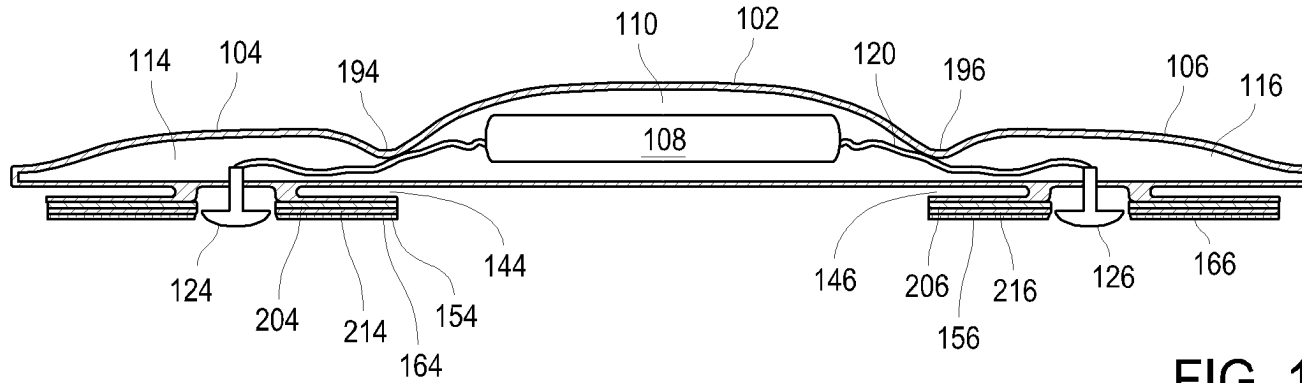


FIG. 1D

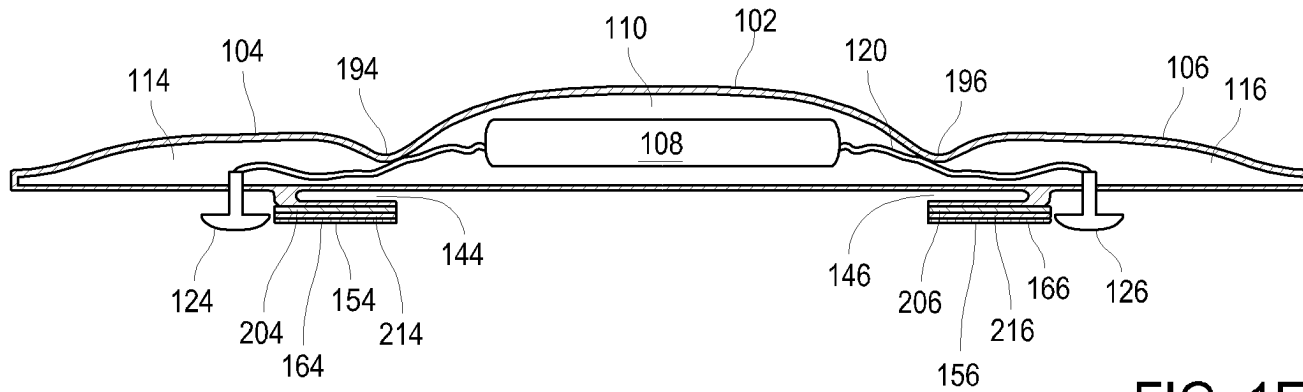


FIG. 1E

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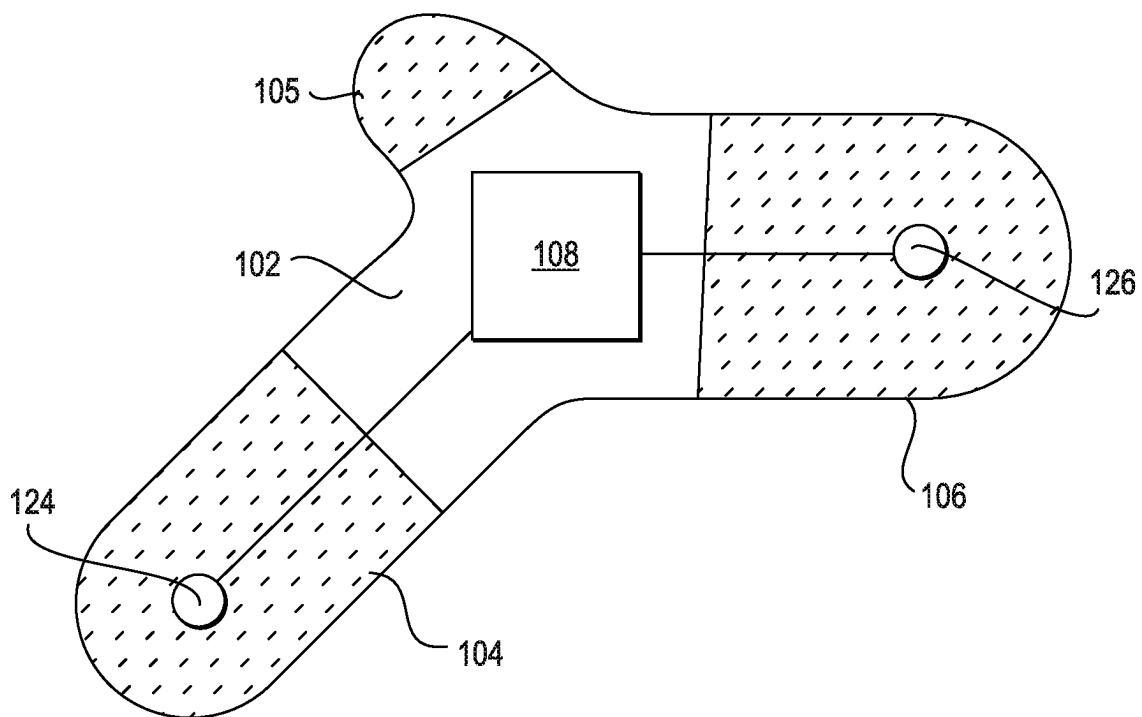


FIG. 1F

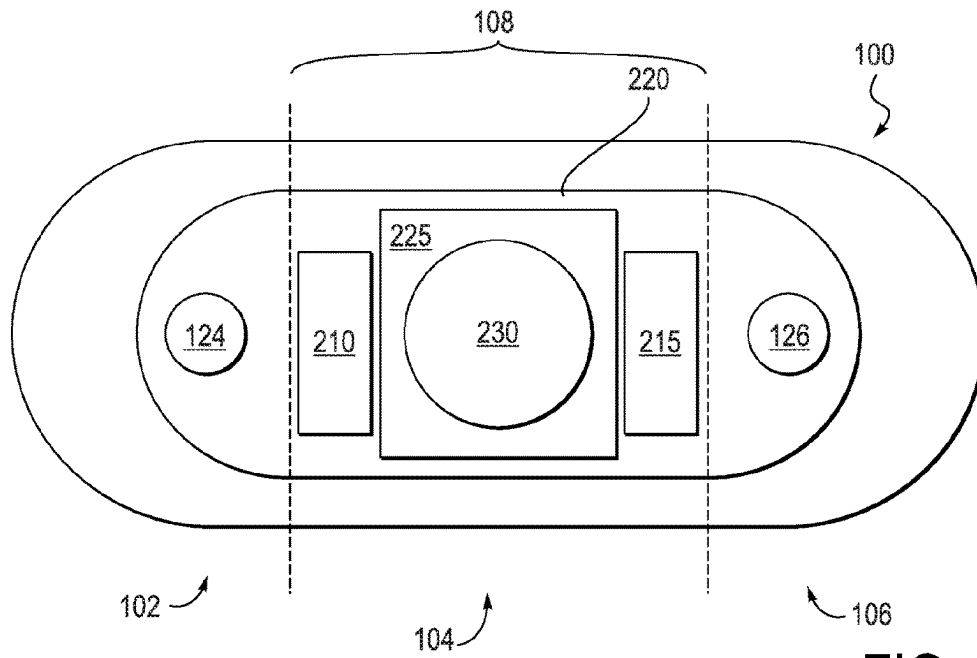


FIG. 2A

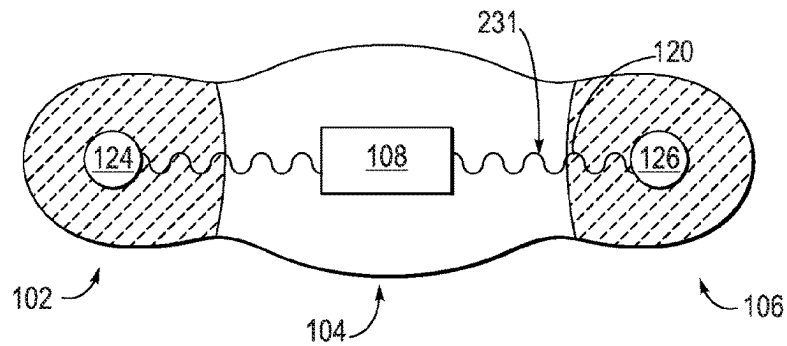


FIG. 2B

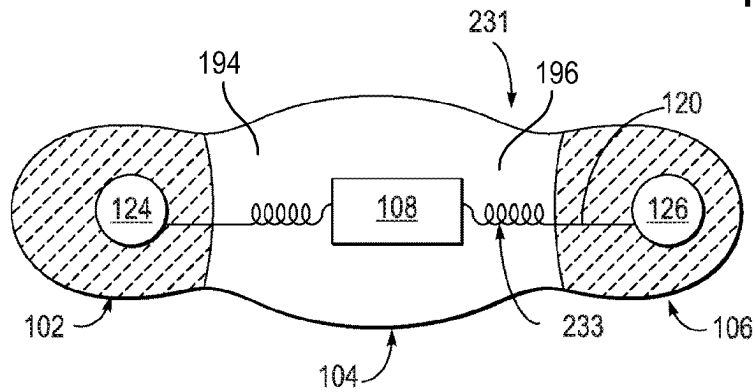


FIG. 2C

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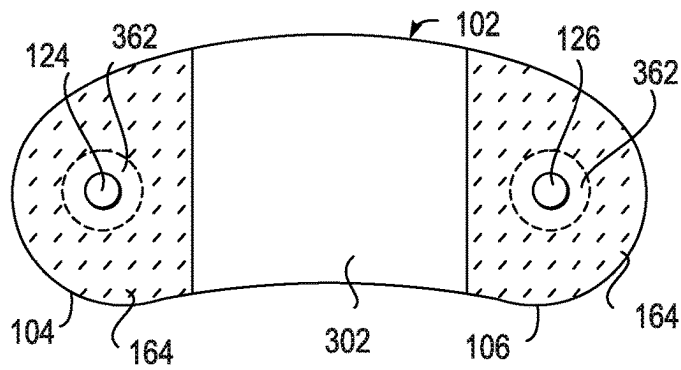


FIG. 3

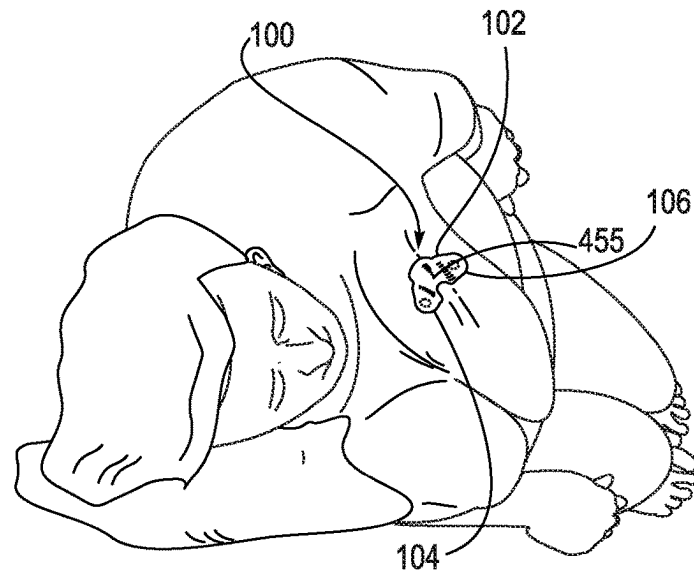


FIG. 4A

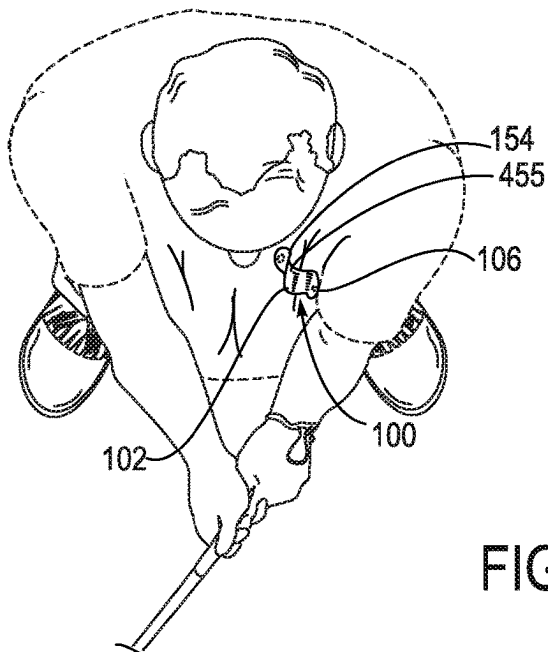


FIG. 4B

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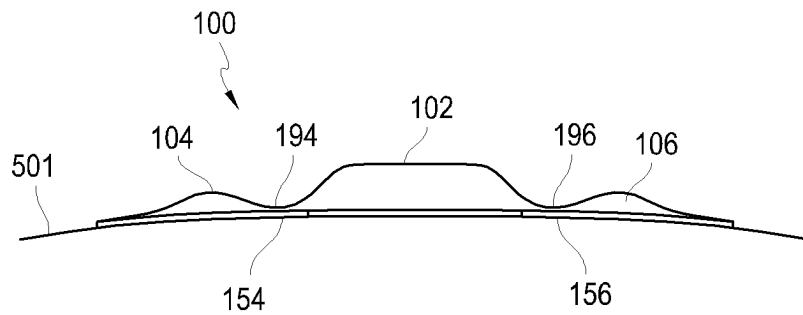


FIG. 5A

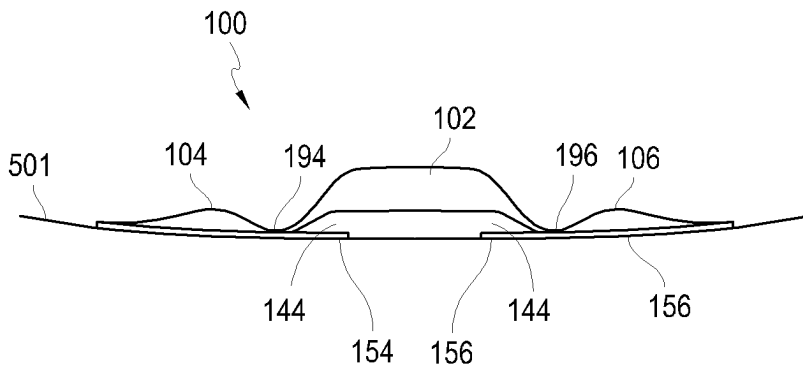


FIG. 5B

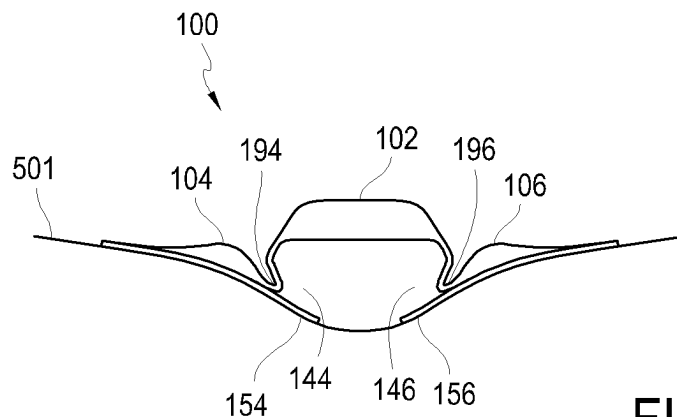
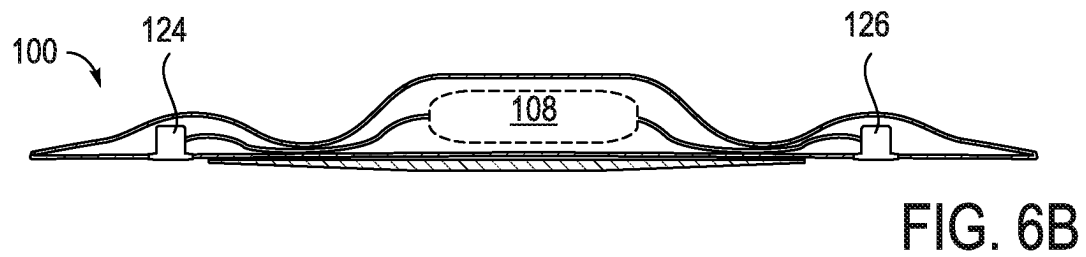
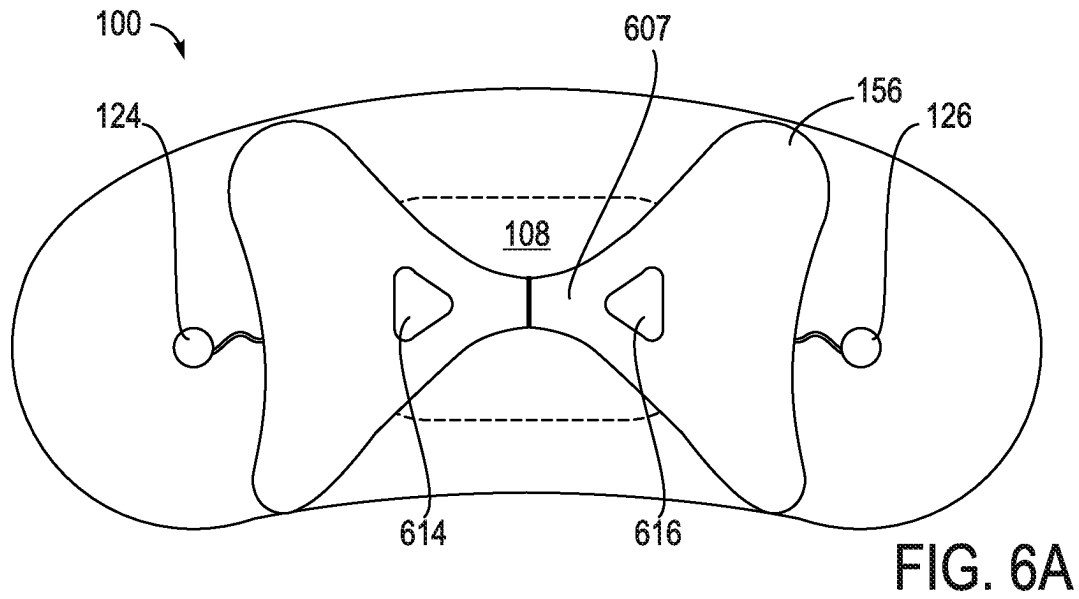


FIG. 5C



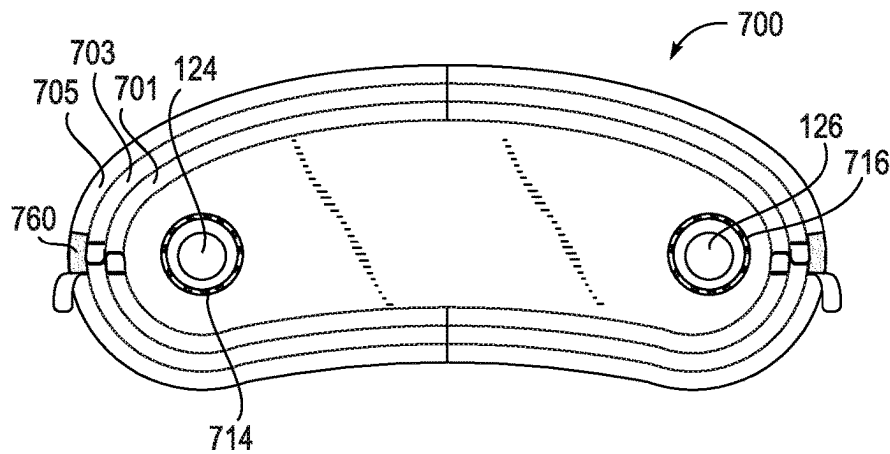


FIG. 7A

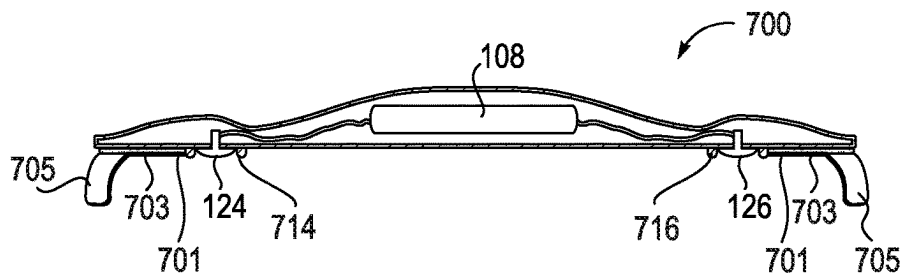


FIG. 7B

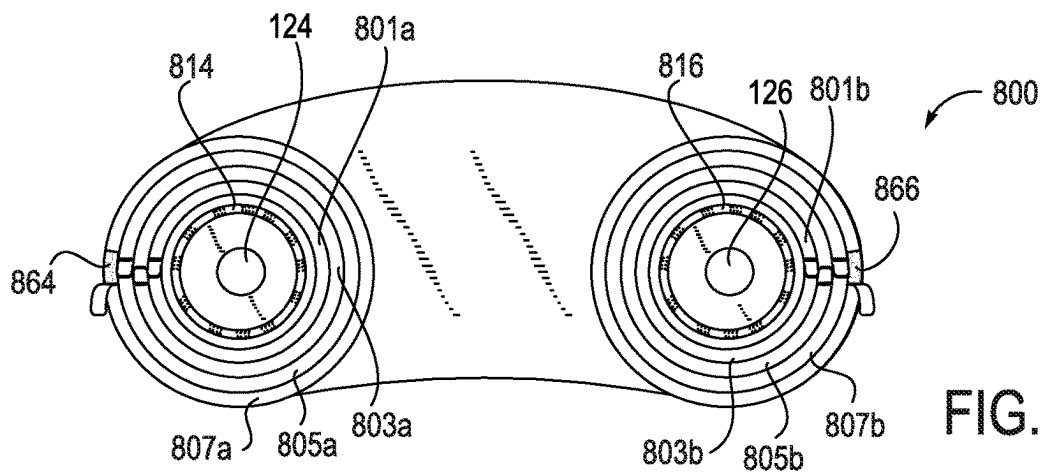


FIG. 8A

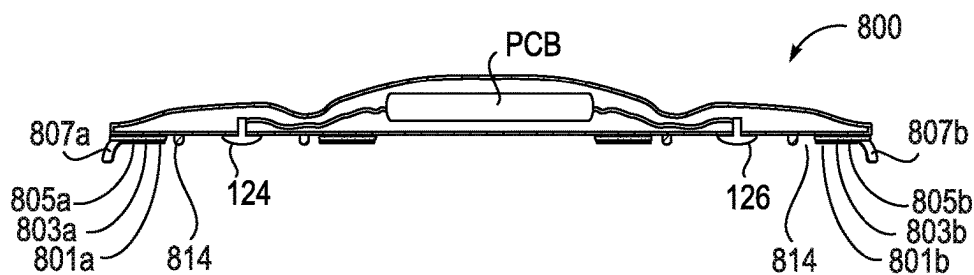


FIG. 8B

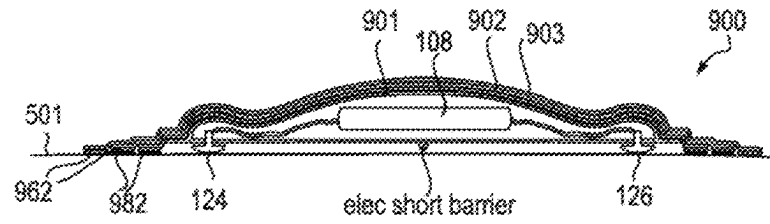


FIG. 9A

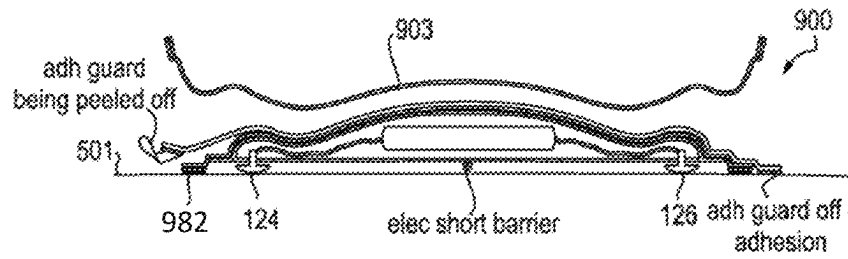


FIG. 9B

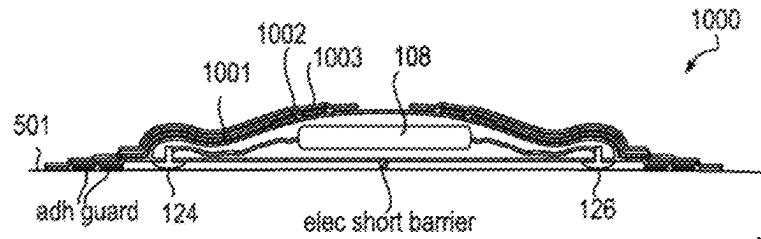


FIG. 10A

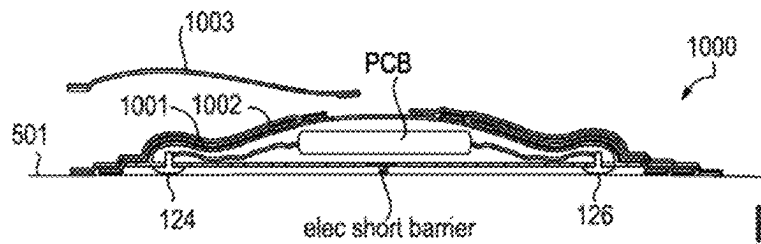


FIG. 10B

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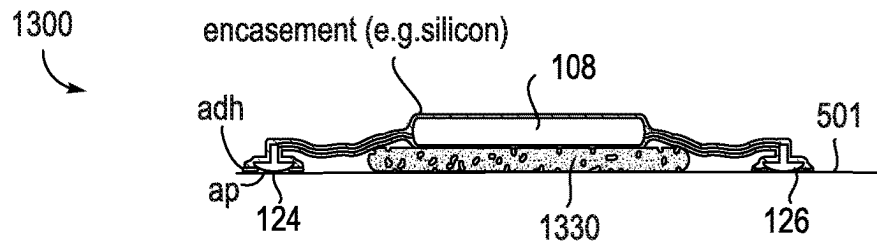


FIG. 11

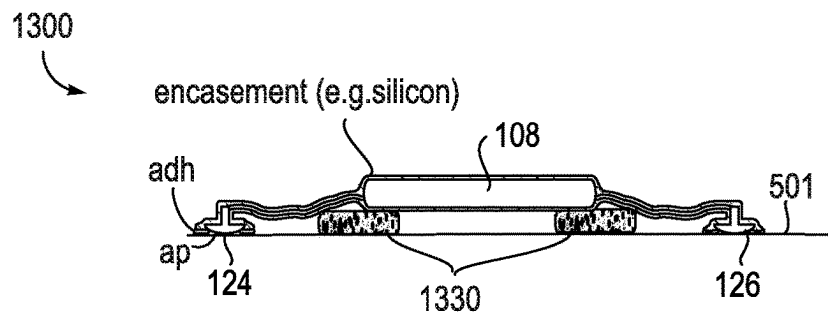


FIG. 12

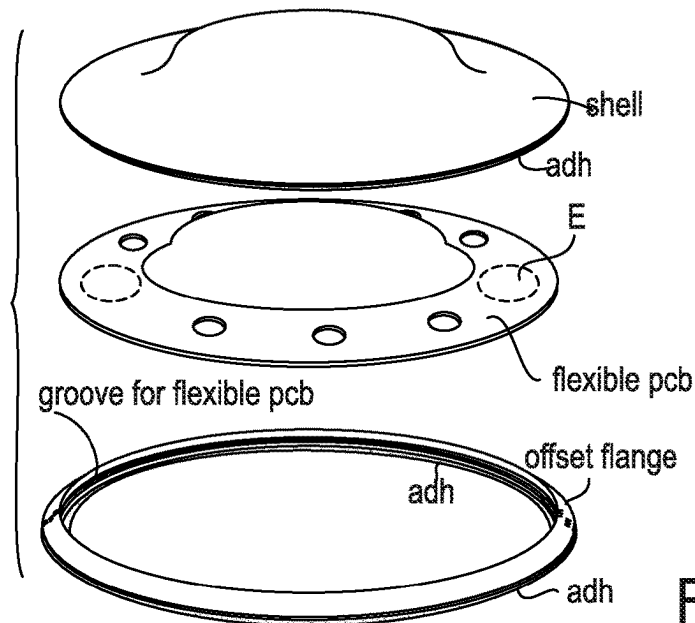


FIG. 13A

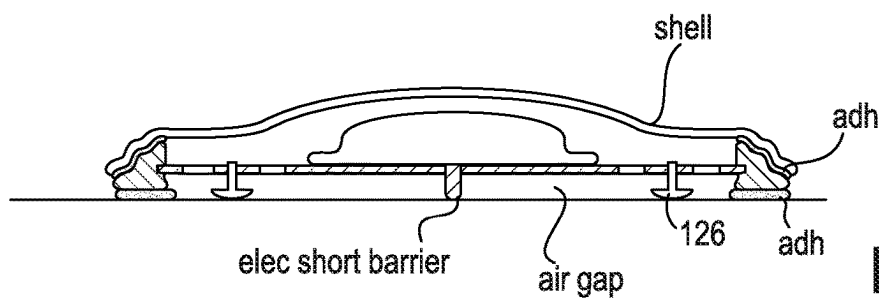


FIG. 13B

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DEVICE FEATURES AND DESIGN ELEMENTS FOR LONG-TERM ADHESION

CROSS-REFERENCE TO RELATED APPLICATIONS

This application is a continuation of U.S. application Ser. No. 17/304,811, filed Jun. 25, 2021, titled “Device Features and Design Elements for Long-Term Adhesion” which claims priority to U.S. application Ser. No. 16/723,208, filed Dec. 20, 2019, titled “Device Features and Design Elements for Long-Term Adhesion” which claims priority to U.S. application Ser. No. 16/138,819, filed Sep. 21, 2018, titled “Device Features and Design Elements for Long-Term Adhesion” which claims priority to U.S. application Ser. No. 15/005,854, filed Jan. 25, 2016, titled “Device Features and Design Elements for Long-Term Adhesion” which claims priority to U.S. application Ser. No. 13/890,144, filed May 8, 2013, titled “Device Features and Design Elements for Long-Term Adhesion” which claims priority to U.S. application Ser. No. 13/563,546, filed Jul. 31, 2012, titled “Device Features and Design Elements for Long-Term Adhesion”, which claims priority to U.S. patent application Ser. No. 13/106,750, filed May 12, 2011, which claims priority to U.S. Provisional Patent Application No. 61/334,081, filed May 12, 2010, entitled “Device Features and Design Elements for Long-Term Adhesion.” All of the aforementioned applications are incorporated by reference as if fully set forth herein.

INCORPORATION BY REFERENCE

All publications and patent applications mentioned in this specification are herein incorporated by reference to the same extent as if each individual publication or patent application was specifically and individually indicated to be incorporated by reference.

FIELD OF THE INVENTION

This application relates to devices worn on a body for monitoring, recording, reporting and/or treating the person wearing the device. Improvements in the device design elements and functionality are disclosed for maintaining the device in contact with and operational for extended periods of time, typically longer than 24 hours.

BACKGROUND OF THE INVENTION

The ability to adhere a medical device to a human body for a long-period of time is dependent on a variety of factors. In addition to the type and nature of the adhesive chosen, another factor is the mechanical design of the device. By design, this refers to, but is not limited to, the device shape, size, weight, flexibility, and rigidity. These design elements are influenced by a number of additional factors, including, but not limited to, where on the body the device will attach and the duration of the attachment, moisture conditions in that area, movement conditions in that area, stretching and contraction in that area, interactions with external factors in that area such as clothing, and purposeful and/or inadvertent interaction between the person wearing the device and the device.

As many are typically used on the body for less than 24 hours, devices have not been designed that can withstand longer-term adhesion. Hence, there is a need to implement device features and design elements that have the ability to

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enhance the likelihood of adhesion of a device to a human body for 24 hours or more, while accommodating the functionality, shape, size, weight, flexibility, and rigidity of a given device.

SUMMARY

In one aspect of the invention, there is an electronic device for long-term adhesion to a mammal. The device has a housing containing an electronic component with a first wing and a second wing integrally formed with the housing. There is an electrode positioned on a bottom surface of each of the wings with the electrodes electrically connected to the electronic component. An adhesive layer is provided for adhesion to a surface of the mammal. The adhesive layer is coated on a portion of the bottom surface of the wings. The adhesive layer is not coated on the electrode or on a bottom surface of the housing.

The electronic component in any of the devices described herein may include a processor having a memory with computer readable instructions to record signals from the first and second electrodes while the electronic device is attached to the mammal. The processor may be configured to only convert signals from the electrodes to digital signals, filter those signals and then store the signals in memory.

In another aspect, the device includes a flap connected to each of the wings. The flaps may extend below the housing. Additionally or alternatively, the adhesive layer is coated on a bottom surface of the flaps.

In another aspect, the device includes a connector segment. In one aspect, the connector segment configured to connect the flaps together. In other aspects, the connector segment is located at least partially below the housing. Still further, the connector segment is not attached to the housing.

In one alternative, the adhesive layer is coated on a bottom surface of the flap.

In still another aspect, the adhesive for adhesion to a surface of the mammal is an adhesive that can absorb fluids.

In another aspect, the adhesive that can absorb fluids is a hydrocolloid adhesive. In another aspect, the adhesive for adhesion to a surface of the mammal is a pressure-sensitive adhesive. The pressure sensitive adhesive is selected from the group consisting of: a polyacrylate, a polyisobutylene, and a polysiloxane. In one alternative, the device includes a diffusion barrier between the adhesive layer and each of the wings. The device may also include an additional adhesive layer and material layer between the wing and the adhesive layer for adhesion to the mammal. The material layer is configured to prevent diffusion of adhesive components from the adhesive layer to the wing. The diffusion barrier may be made from polyester or other suitable synthetic material.

In one aspect of the device, all or substantially all of the electronic components are within the housing. In another aspect, the wing is free from electronic components. In one aspect, the wing is more flexible than the housing. In one alternative, the wings and the housing are made from the same material. In another aspect, the wings and the housing are made from different materials. In another, the wings are made from a fabric. In still another aspect, the material used to make the wings includes a synthetic fiber. In another alternative, the wing and the flap are composed of the same material.

In another alternative, the device includes a hinge portion between the housing and wing. The hinge portion is configured to allow the device to bend between the housing and the wing. In one aspect, the hinge portion exists between a rigid

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portion of the device and a flexible portion of the device. In one alternative, the rigid portion of the device corresponds to the portion of the housing including the electronics and the flexible portion of the device includes a wing

In one aspect, the bottom surface of the wing and the bottom surface of the flap are contiguous. In another aspect, the bottom surfaces of the wings, the flap, and the connectors are contiguous. In still other aspects, the flaps and the connector are contiguous.

In another aspect, the connector has at least one hole extending it. The hole may have any of a number of shapes such as circular, oval, round, or triangular.

In one aspect, the housing is thicker at a center of the housing than at edges of the housing.

In another aspect of the device, the housing is unattached to the mammal when the electrodes are in contact with the mammal.

In another alternative aspect of a device for long-term adhesion to a mammal, the device includes a housing with a first wing extending laterally from the housing and a second wing extending laterally from the housing without overlapping the first wing. There is a first electrode positioned on a bottom surface of the first wing and a second electrode positioned on a bottom surface of the second wing. An electronic memory is positioned within the housing. The electronic memory is configured to receive and store electronic signals from the first and second electrodes while the electronic device is attached to the mammal. There is also an adhesive layer on a portion of a bottom surface of the first wing and the second wing. The adhesive is not on a bottom surface of the housing. When the device is worn on the mammal, only the adhesive layer(s) are attached to the mammal.

In one aspect, the portion of the bottom surface of the first wing and the second wing does not include the first and second electrodes. In one device aspect, the first wing, the second wing, and the housing are formed from the same material. In still another, the first wing, the second wing and the housing integrally form a monolithic structure. In other aspects, an angle formed by the first wing, the second wing, and the housing is between approximately 90° and 180°. In one variation, the angle is approximately 180°. In another variation, the angle is approximately 135°.

In still other embodiments, there is a first hinged portion between the first electrode and the processor and a second hinged portion between the second electrode and the housing.

In a further aspect, at least a portion of the body uncovered is not adhered to the mammal when signals from the electrodes are being recorded in memory.

In another aspect, the device includes a first flap connected to the first wing medial to the first electrode and a second flap connected to the second wing medial to the second electrode. Each nap may extend below the housing.

The device may also include a connector segment configured to connect the flaps together. In one aspect, the connector segment is located at least partially below the housing, but is not attached to the housing.

In another aspect, there is an electronic device that has a patch including a housing containing an electronic component. There is an electrode positioned on a bottom surface of the patch, the electrode electrically connected to the electronic component. There is a first adhesive strip extending around the perimeter of the patch and a second adhesive strip extending around the perimeter of the first adhesive strip. In one aspect, the first adhesive cover over the first adhesive strip and a second adhesive cover over the second adhesive

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strip. The first and second adhesive covers may be configured to be separably removed from the first and second adhesive strips. In one alternative, the first adhesive strip extends between the first and second adhesive covers. In another alternative, the adhesive in the first and the second adhesive strips is an adhesive that can absorb fluids. In still another aspect, the adhesive that can absorb fluids is a hydrocolloid adhesive. In one alternative, the adhesive in the first and the second adhesive is a pressure-sensitive adhesive. In some aspects, the pressure-sensitive adhesive is a polyacrylate, a polyisobutylene, or a polysiloxane.

In one alternative, the second adhesive strip partially overlaps the first adhesive strip. In another aspect, the second adhesive strip is attached to a shell, the shell overlapping the first adhesive strip.

In still another alternative device for long-term adhesion to a mammal, the device includes a patch having a housing with an electronic component contained therein. There is an electrode positioned on a bottom surface of the patch. The electrode electrically connected to the electronic component. There is a porous foam pad configured to be positioned between the electronic component and the mammal. In one aspect, the porous foam pad comprises a biocompatible foam material. In one variation, the porous foam pad can absorb fluids. In still another aspect, the porous foam pad is attached to the housing. In another, the porous foam pad is configured to be attached to the mammal. In another request, the porous foam pad can absorb fluids.

In one aspect of a method of applying an electronic device, there is a step of removing a first adhesive cover from the first wing of the electronic device to expose an electrode and an adhesive coated on a bottom surface of a first wing. There is a step of placing the exposed electrode into contact with the mammal by adhering the adhesive coated bottom of the first wing to the mammal. There is also a step of removing a second adhesive cover from the second wing of the electronic device to expose an adhesive coated on a bottom surface of the second wing and another exposed electrode. There is also a step of placing the another exposed electrode into contact with the mammal by adhering the adhesive coated bottom of the second wing to the mammal. After performing the removing and the placing steps, the housing is unattached to the mammal, but is held in position on the mammal using the adhesive coated bottoms of the first and the second wings.

In one alternative method of attaching a device, the electronic device includes a first nap connected to the first wing and a second flap connected to the second wing. The first and second flaps each extend below the housing. The step of removing a first adhesive cover from the first wing may also include exposing an adhesive coated on a bottom surface of the first flap. The step of removing a second adhesive cover from the second wing may also include exposing an adhesive coated on a bottom surface of the second flap.

In another alternative method of attaching a device, after performing the removing and the placing steps, the housing is held in position on the mammal using only the adhesive coated bottoms of the first wing, the second wing, the first flap and the second flap.

In an alternative aspect of a method of applying an electronic device to a mammal for long-term adhesion, the method includes removing a first adhesive cover from the first wing of the electronic device to expose an electrode and an adhesive coated on a bottom surface of the first wing. There is also a step of removing a second adhesive cover from the second wing of the electronic device to expose an

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adhesive coated on a bottom surface of the second wing and another exposed electrode. There is a step of placing the exposed electrodes into contact with the mammal by adhering the adhesive coated on the bottom of the first and the second wings to the mammal. After performing the removing and the placing steps, the housing is unattached to the mammal, but is held in position on the mammal using the adhesive coated bottoms of the first and the second wings.

There is also provided a method of applying an electronic device to a mammal for long-term adhesion wherein the electronic device includes a patch. The patch includes an electronic component along with an electrode positioned on a bottom surface of the patch and electrically connected to the electronic component. There is a first adhesive strip extending around the perimeter of the patch and a second adhesive strip extending around the perimeter of the first adhesive strip. One aspect of a method of applying the device includes a step of removing an adhesive cover from the second adhesive strip of the electronic device. There is a step of applying pressure to the second adhesive strip to adhere the second adhesive strip to the mammal such that the electrode is in contact with the mammal. Then, after a period of time, removing an adhesive cover from the first adhesive strip of the electronic device. Next, there is the step of applying pressure to the first adhesive strip to adhere the first adhesive strip to the mammal such that the electrode remains in contact with the mammal.

In another alternative method of applying an electronic device to a mammal for long-term adhesion, the electronic device includes a patch, an electronic component, and an electrode positioned on a bottom surface of the patch and electrically connected to the electronic component. There is a first adhesive strip extending around the perimeter of the patch. The method includes a step of applying pressure to a first adhesive strip to adhere the first adhesive strip to the mammal such that the electrode is in contact with the mammal. After a period of time, placing a second adhesive strip around the perimeter of the first adhesive strip. Then there is the step of applying pressure to the second adhesive strip to adhere the second adhesive strip to the mammal such that the electrode remains in contact with the mammal.

Any of the above described devices may include additional aspects. A device may also include a first wire connecting the first electrode and the processor or an electronic memory and a second wire connecting the second electrode and the processor or an electronic memory. The first and second wires extend within the body and the first and second wings. In one aspect, the first and second wires extend within and are completely encapsulated within the body and the first and second wings. In one aspect, a conduit is provided within the body and the wings and the wires pass through the conduit. In one alternative, the conduit extends from the processor or electronic memory to an electrode so that the wire is completely within the conduit. In still other aspects of the devices described above, the first and second wires connecting the electrodes to the processor or electronics each include slack between the electrode and the processor. In one aspect, the slack is located in a portion of each wing that is configured to bend or flex. In another aspect, the slack is a portion of the wire within the wing and at least partially coiled about the first or the second electrode. In still other aspects, the slack is provided by a portion of the wire formed into a coil, a wave pattern, or a sinusoidal pattern along its length the connection point on the electronics to the connection point on the electrode.

In still other alternatives, the devices described above may be applied to any of a wide variety of conventional

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physiological data monitoring, recording and/or transmitting devices. Any of the improved adhesion design features and aspects may also be applied to conventional devices useful in the electronically controlled and/or time released delivery of pharmacological agents or blood testing, such as glucose monitors or other blood testing devices. Additional alternatives to the devices described may include the specific components of a particular application such as electronics, antenna, power supplies or charging connections, data ports or connections for downloading or off loading information from the device, adding or offloading fluids from the device, monitoring or sensing elements such as electrodes, probes or sensors or any other component or components needed in the device specific function. In still other aspects, the electronic component in any of the above devices is an electronic system configured for performing, with the electronic signals of the mammal detected by the electrodes, one or more or any combination of or the following electronic functions: monitoring, recording, analyzing, or processing using one or more algorithms electronic signals from the mammal. Still further, any of the devices described above may include appropriate components such that the device is used to detect, record, process or transmit signals or information related to signals generated by a mammal to which the device is attached including but not limited to signals generated by one or more of EKG, EEG and/or EMG.

BRIEF DESCRIPTION OF THE DRAWINGS

The novel features of the invention are set forth with particularity in the claims that follow. A better understanding of the features and advantages of the present invention will be obtained by reference to the following detailed description that sets forth illustrative embodiments, in which the principles of the invention are utilized, and the accompanying drawings of which:

FIG. 1 is a top view of a patch having two wings;

FIG. 1A is a representative cross-section of an embodiment of the patch in FIG. 1;

FIG. 1B is a representative cross-section of another embodiment of the patch in FIG. 1;

FIG. 1C is a representative cross-section of another embodiment of the patch in FIG. 1;

FIG. 1D is a representative cross-section of another embodiment of the patch in FIG. 1;

FIG. 1E is a representative cross-section of another embodiment of the patch in FIG. 1;

FIG. 1F is a top view of a patch having three wings illustrating an alternative electrode-electronics-electrode orientation;

FIG. 2A is a schematic drawing of the electronics contained within a patch;

FIG. 2B is a schematic drawing of a patch with wiring having slack in the form of undulations between electronics and electrodes;

FIG. 2C is a schematic drawing of a patch with wiring having slack in the form of a coil between electronics and electrodes;

FIG. 3 is the bottom view of a patch having adhesive thereon;

FIG. 4A shows a patch as worn by a person rolled to the side;

FIG. 4B shows a patch as worn by a person playing golf;

FIG. 5A shows a patch in response to a concave bend of the skin;

FIGS. 5B and 5C show a patch in response to a convex bend of the skin;

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FIG. 6A is a bottom view of a patch having a connector between two flaps;

FIG. 6B is a cross-section of the patch of FIG. 6A;

FIG. 7A is a bottom view of a patch having multiple covers forming strips of adhesive;

FIG. 7B is a cross-section of the patch of FIG. 7A;

FIG. 8A is a bottom view of a patching having multiple covers forming strip of adhesive around each electrode;

FIG. 8B is a cross-section of the patch of FIG. 8A;

FIGS. 9A and 9B show a patch having multiple layers formed thereon;

FIGS. 10A and 10B show a patching having multiple layers formed thereon, each layer having multiple patches of adhesive;

FIG. 11 shows a patch having an open cell support;

FIG. 12 shows a patch having an annular open cell support;

FIG. 13A shows a patch having a protective shell thereon; and

FIG. 13B shows a cross-section of the patch of FIG. 13A.

DETAILED DESCRIPTION

The following device features and design elements can be implemented into any device being adhered to the human body for a long-period of time, typically greater than 24 hours. As an example, the following device features and design elements can be used for long-term adhesion of a cardiac rhythm monitoring patch ("patch") to the chest of a person.

Referring to FIGS. 1 and 1A, a patch 100 for long term adhesion includes a housing 102. The housing 102 can be formed from any flexible, durable material, such as a bio-compatible polymer, for example silicone. The housing 102 can include electronic components 108 therein. As shown in FIG. 2, the electronics 108 can include a printed circuit board 220, a battery 225, and a communications port mounted on the printed circuit board 220. The printed circuit board 220 can include analog circuits 210, digital circuits 215, and an activation or event notation button or switch 130. The electronics 108 can be used, for example, to record continuous physiological signals from a mammal wearing the patch 100. A system for continuously recording data is described further in co-owned U.S. application Ser. No. 11/703,428, filed Feb. 6, 2007, the entire contents of which are incorporated by reference herein.

As shown in FIGS. 1 and 1A, wings 104, 106 can be connected to the housing 102. The wings 104, 106 can be integral with the housing 102 and, in some embodiments, can be formed of the same material as the housing 102. The wings 104, 106 can be more flexible than the electronic components 108, which can be substantially rigid. An electrode 124, 126 can extend through a bottom surface of each wing 104, 106. The electrodes can be positioned to detect an ECG of a mammal wearing the patch 100 for processing by the electronics 108. For example, the electrodes can be more than 2 cm apart, such as more than 3 cm apart, for example at least 6 cm apart. The electrodes 124, 126 can be integral with the wings 104, 106 so as to be inseparable from the wings 104, 106 when the patch is in use.

For a patch 100 that is entirely flexible and can conform, stretch, and adapt to the movement and conditions of the chest underneath the device, adhesive can be placed over the entire surface of the device that is in contact with the body, except for areas where sensors, electronics, or others elements such as electrodes are interacting with the body related to the functioning of the device may be incorporated.

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Thus, as shown in FIG. 3, an adhesive layer 166 can coat the bottom of the patch 100 for attachment to the skin. For a patch 100 in which there may be some areas that are not completely flexible and may not be able to stretch or contract (e.g., the electronics 108), adhesive may be excluded from the portion of the patch 100 underneath these areas. Thus, for example, the bottom surface 302 of the housing 102, which contains the electronics, can remain free from adhesive. As shown in FIG. 1A, by not coating adhesive on a bottom surface of the housing 102, the housing 102 can float above the adhered portions, allowing for increased flexibility of the patch, as will be discussed further below. Further, as shown in FIG. 3 the bottom surface of the electrodes 124, 126 can remain free of adhesive. For example, a ring 362 without adhesive can be formed around each electrode 124, 126 to separate the electrodes from the adhesive 164. The adhesive can be, for example, a pressure-sensitive adhesive, such as polyacrylate, polyisobutylene, or a polysiloxane. Alternatively, the adhesive can be a hydrocolloid which advantageously absorbs water.

The wings 104, 106 and the housing 102 can form a smooth, contiguous outer surface to the patch 100. As shown in FIG. 1A, when viewed from the top, the housing 102 and wings 104, 106 can together form an oblong substantially oval shape. Further, the housing 102 can have a thickness that is greater than the thickness of the wings 104, 106. The housing 102 and each of the wings 104, 106 when viewed in profile, can each form a dome with a height that is greater at the center than at the ends of the respective component, i.e. some or all of the components can be tapered at the ends and/or sides.

The electronics 108 can extend along only a portion of the distance between the electrodes 104, 106. For example, the electronics can occupy less than 90% of the distance between the electrodes, for example less than 80%. By having the electronics 108 in a relatively limited space between the electrodes 124, 126, the flexibility of the patch 100 can be increased.

The housing 102 can provide a watertight enclosure 110 for electronic components 108 of the patch 100. The electronics 108 can be unattached to the housing 102 such that the electronics 108 are free to move within the watertight enclosure 110. Allowing the relatively rigid electronics 108 to move freely within the flexible housing 102 advantageously enhances the overall flexibility of the patch 100. The wings 104, 106 can each have a watertight enclosure 114, 116 formed therein, which can be contiguous with the watertight enclosure 110 of the housing 102.

Wiring 120 or other suitable electrical connections can connect the electrodes 124, 126 with the electrical components 108 of the housing. In some embodiments, as shown in FIGS. 1B-1E, the contiguous nature of the enclosure 110 and the enclosures 114, 116 allows the wiring 120 to extend within the patch 100 from the electrodes 124, 126 to the electronic components 108. In other embodiments, one or more channels, tubes, or conduits are provided between the housing 102 and the wings 104, 106, to provide space for the wiring 120. The tube or channel may be straight or curved. In use, the wire 120 positioned in the enclosures 110, 114, 116 or in the tube or channel may move relative thereto in order to remain flexible within the housing. In one aspect, the flexible channels or tubes are formed within the device housing so that the housing, as it is being stretched, does not affect the ability of the components, such as wires, that may connect more rigid structures, to move or elongate.

As shown in FIG. 1, the wire 120 is straight with a direct line of connection between the electrodes 124, 126 and the

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electronics 108. FIG. 1 illustrates an embodiment where the length of the wires 120 connecting the electrodes 124, 126 to electronics 108 are about the same distance as the spacing between the electrode connection point on electronics 108 and the electrodes 124, 126. FIG. 1F also illustrates a straight line type connection where wire 120 length is nearly the same as the spacing between the electronics 108 and the electrodes 124, 126. However, as a patient moves, the patch 100 flexes along with patient movement. As shown in FIGS. 4B and 5C, patch flexion may be severe and is likely to occur during long term monitoring. In order to address the possible dislocation or breakage of the wire 120, the length or shape of the wire 120 may be selected to permit patch flexion to occur with little risk of wire 120 pulling from the electrode or electronics. Numerous alternatives are possible to compensate for patch flexion. Exemplary confirmations include undulations or zig-zags 231 as shown in FIG. 2B, coils 233 as shown in FIG. 2c, or a configuration that partially or fully wraps around an electrode. In some embodiments, other components, such as the circuit board or electrodes, can alternatively or additionally contain additional length to help accommodate stretch or displacement. When the patch 100 is attached to a mammal, the slack in the wiring 120 allows the patch 100 to flex while not placing stress on the wiring 120.

While the illustrated embodiments of FIGS. 1A-1D show only two wings and show the electrodes and electronics in a direct line in an approximate 180 degree alignment of electrode 124 to electronics 108 to electrode 126, other configurations are possible. For example, as shown in FIG. 1F, the wings 104, 106 are arranged in an orientation less than 180 degrees. In the illustrated embodiment, the angle formed by the electrodes and the electronics is about 135 degrees. Other ranges are possible so long as electrode spacing is provided to permit ECG monitoring. The orientation of the wings 104, 106 to the housing 102 also illustrates the use of an additional adhesive tab 105. Tab 105 is shown as a semicircular extension of the body 102. The bottom of tab 105 can include adhesives as described herein and is used to provide additional anchoring of the patch to the patient. The tab 105 may be formed in any of a number of different shapes such as rectangles, ovals, loops or strips. Further, in some embodiments, the tab 105 can function similar to a wing, e.g., include an electrode therethrough that connects to the electronics 108.

Referring to FIGS. 1A-1D and 2B-2C, a hinge portion 194, 196 in the patch 100 can extend between each electrode 124, 126 and the electronics 108. The hinge portions 194, 196 can have a thickness less than the thickness of surrounding portions of the patch 100. For example, if the hinge portions 194, 196 are in the wings 104, 106, then the thickness can be less than adjacent portions of the wings. Likewise, the hinge portions 194, 196 can have a width less than adjacent portions of the patch 100, e.g., less than adjacent portions of the wings 104, 106. Alternatively, the hinged portion can be formed by the adjunct between a rigid portion, i.e. the electronics 108, and a more flexible portion. The hinged portion allows the patch 100 to bend between the housing 102 and wings 104, 106 to compensate for any movement caused by the patient. As shown in FIGS. 2B and 2C, the slack in the wiring 120 can be placed at or proximal to the hinge portions 194, 196 to allow for bending at the hinge portions 194, 196 without pulling or breaking the wiring 120.

Referring to FIGS. 4A and 4B, having adhesive on the bottom of the patch 100 except in the areas substantially around the electrodes and directly underneath the housing

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102 can create a floating section 455 over the skin of the mammal to which the patch 100 is attached. The floating section 455 can house the more rigid or less flexible electronic components while the flexible wings 104, 106 can be adhered to the skin and provide the flexibility necessary to hold the patch 100 in place. As a result of this selective use of adhesive areas and non-adhesive areas, the limitation on device flexibility imposed by the less flexible floating section can be mitigated or reduced by hounding the floating section with one or more adhered flexible areas. The flexible sections can thus adhere to the body if the underlying portion of the body is stretched and/or contracted while the floating section is free to move above the skin, for example if the person wearing the device rolls over (as shown in FIG. 4A) or is involved in activities that can otherwise cause movement of the skin (as shown in FIG. 4B).

Referring back to FIGS. 1B-1E, each wing 104, 106 can include a material layer 214, 216 between the adhesive 164, 166 and the wings 104, 106. The material layer 214, 216 can be, for example, a polyester layer. The material layer 214, 216 can be attached to the patch 100 with a layer of adhesive 204, 206. The adhesive 204, 206 can be the same as the adhesive 164, 166 or different. For example, the adhesive 204, 206 could be a silicone adhesive. The material layer 214 can serve as a barrier to prevent diffusion or migration of adhesive components, such as a tackifier, from the adhesive 164, 166 into the wings 104, 106 or housing 102. The material layer 214 can thus advantageously serve to maintain the strength of the adhesive 104, 106 over time.

Referring still to FIGS. 1B-1E, the patch 100 can further include a first flap 154 connected to the first wing 104 and a second flap 156 connected to the second wing 106. The flaps 154, 156 can both extend from a position on the wings 104, 106 medial to the electrodes to a position below the housing 102, such as below the electronics 108. The flaps 154, 156 can remain unattached to the housing 102. As a result, gaps 144, 146 can be formed between the flaps 154, 156 and the housing 102. The gaps can provide additional "floating" for the housing 102 and the relatively rigid components 108 contained therein.

In some embodiments, shown in FIG. 1B, the flaps 154, 156 can be attached to the wings 104, 106 with adhesive 134, 136. The adhesive 134, 136 can be the same as the adhesive 164, 166 or different. For example, the adhesive 134, 136 could be a silicone adhesive. In other embodiments, shown in FIGS. 1C-1E, the flaps 154, 156 can be integral with the wings 104, 106. For example, the flaps 154, 156 can be solvent welded to and/or formed during the molding process of the wings 104, 105 such that hinges 194, 196 form below the wings 104, 106. Additionally or alternatively, one or more of the flaps 154, 156 may be separately attached to the wings 104, 106. In some embodiments, shown in FIGS. 1B and 1C, the materials making up the flaps 154, 156 can extend all the way to the lateral edge of the patch 100. In other embodiments, shown in FIG. 1D, a flap can extend on each side of the electrodes, i.e. one flap can extend medially and the other laterally. In some embodiments, the lateral and medial—extending flaps are part of the same annular flap. In other embodiments, shown in FIG. 1E, the flaps and materials making up the flaps extend only from a position medial to the electrodes underneath the housing.

The Flaps 154, 156 may be positioned in virtually any relationship to the adhered flexible area such that, when attached in use, the attachment of the flap or flaps effectively counteracts the expected external forces acting on the device, specifically those forces that may dislodge the adhered flexible areas. Further, in embodiments such as that

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shown in FIG. 1F where there are more than two wings, there can be a flap corresponding to each additional wing.

The adhesive layers **164**, **166** can coat all or a portion of the bottom of each of the flaps **154**, **156**. In some embodiments, the adhesive **164**, **166** extends continuously from the bottom surface of the wings **104**, **106** to the bottom surface of the flaps **154**, **156**, except for areas proximate to the electrodes **124**, **126**. Further, the top surface of the flaps **154**, **156**, i.e. the surface closest to the housing **102**, can remain free of adhesive to ensure that the housing **102** remains floating. In some embodiments, the only portion of the patch **100** including adhesive for adhesion to the skin can be the flaps **154**, **156**.

Referring to FIGS. 5A-5C, the naps **154**, **156**, can provide hinge-like behavior for the patch **100**. Thus, as shown in FIG. 5A, if the skin **501** is stretched or bent in a concave manner, the gaps **144**, **146** between the flaps **154**, **156** and the housing **102** can approach zero such that the patch **100** can sit substantially flat on the skin **501**. As shown, the hinge portions **194**, **196** between the housing **102** and wings **104**, **106** can provide additional flexibility for concave bends by flattening as the patch **100** is stretched. In contrast, as shown in FIGS. 5B and 5C, as the skin **501** is bent in an increasingly convex manner, the gaps **144**, **146** between the flaps **154**, **156** and the housing **102** can increase, thereby allowing the flexible wings **104**, **106** to remain adhered to the skin and the rigid housing **102** to float above skin. As shown, the hinge portions **194**, **196** between the housing and the wings **104**, **106** can provide additional flexibility for convex bends by folding inward as the patch **100** is bent.

When placed substantially flat on the skin **501**, the patch **100** can have a height that extends no more than 2 cm off of the skin, such as no more than 1.5 cm off of the skin, when lying flat on the patient and no more than 4 cm, such as no more than 1 cm off of the skin when floating above the skin. The relatively low height of the patch **100** can enhance long-term adhesion by reducing the potential for the patch **100** to snag or rip off of the skin.

Advantageously, the flaps **154**, **156** can function as anchors for adhesion that mitigates shear force. The flaps **154**, **156** can provide a different direction for the acute and chronic forces being experienced by the device due to stretching, contraction, or torsion to be spread out over both the flap as well as the flexible adhesive areas. Further, by pre-aligning the orientation of the floating section, adhered flexible area and the flaps, the device may be better able to tolerate (i.e., remain attached to the body and in use) and/or tailor the interaction with the forces acting on the device in order to better withstand the acute or chronic forces being experienced by the device. Tailoring the response of the device to the expected forces is one

Because the flaps can be used to counteract forces acting on a particular device, it is to be appreciated that the dimensions, flexibility, attachment technique, and/or orientation between a flap and another component may vary depending upon the purpose of a particular flap. Accordingly, a flap may have the same or different characteristics from another flap or component of the device. In one aspect, at least one flap is more flexible than the other flaps in a particular device. In another aspect, each of the flaps has similar flexibility. In still another aspect, at least one flap is more flexible than the device component to which it is attached or from which it originates. In still another aspect, at least one flap is less flexible than the device component to which it is attached or from which it originates.

Referring to FIGS. 6A and 6B, in one embodiment, the flaps **154**, **156** may be augmented by a connector segment

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607 used to join the flaps together. The connector segment **607** can extend below the housing **102**, but remain unattached to the housing **102**. As shown in FIG. 6A, the flaps **154**, **156** and the connector **607** can together form a butterfly shape. In one embodiment, the connector segment **607** and the flaps **154**, **156** are formed from a single piece of material. The connector segment **607** can be made of the same material as the flaps **154**, **156** or of different material. In one embodiment, the bottom surface of the connector is covered with adhesive. In another embodiment, the bottom surface of the connector does not include any adhesive. Further, as shown in FIG. 6B, the connector segment **607** can be thicker in the middle, under the housing **102**, than near the edges, i.e., closer to the electrodes. The variable thickness can help prevent the connector segment **607** from capturing moisture thereunder. The connector segment **607** can advantageously prevent the device from flipping when attached to the patient

The connector segment **607** can include one or more holes **614**, **616**. In some configurations, the connector segment may trap moisture and/or inadvertently stick to the body. The holes **614**, **616** can advantageously minimize the potential for undesired sticking or moisture collection. The size, shape and placement of the holes mitigate or reduce the collection of moisture and/or undesired adhesive still providing a connector with sufficient structural integrity (i.e. the connector allows the flaps to be connected to one another in order to prevent them from folding). Additionally or alternatively, the connector holes could also be made to preferentially allow forces to be distributed along certain axes of the connector in order to further maximize the ability of the device to adhere long-term in the face of significant acute and chronic forces due to stretching, contraction, and torsion.

Adhesive can be selectively applied to the connector and/or naps to provide the desired body attachment locations depending upon the specific use of the device. For example, one piece of material including flaps and the connector can be adhered along two or more edges and/or with adhesive only covering certain areas. In another aspect, at least a portion of the skin-contacting surface of the unitary nap connector structure does not include any adhesive. Additionally or alternatively, the connector segment incorporating the flaps may be integral parts of the larger device housing (e.g. could be molded as part of the device housing or enclosure).

In some embodiments, the patch **100** can include one or more release liners to cover parts of the adhesive prior to adhesion. As is particular to devices having multiple adhesive areas and/or multiple adhesive components (i.e., flaps and flexible sections), the manner of applying the device may be specifically detailed in order to ensure that the device and the adhesive portions are properly engaged. In one particular aspect, the release liners are removed in a particular order to minimize the likelihood that the device adhesive is misapplied. For example, a portion of the adhesive may be exposed first and used to affix the device to the body. Thereafter, a second set of adhesive liners may be removed to expose and affix one or more flaps to the body. A stepwise adhesive exposure method may be implemented during device application such that elements, such as the one or more flaps do not fold on themselves, for example.

Breaking up the areas in which the adhesive is used to adhere the device, whether it be splitting it up to rigid areas, to create flaps, to create connector segments with holes, or any of the other techniques described above may also have benefits in terms of preventing moisture bridges that could act as conducting pathways between electrical sensing ele-

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ments, such as electrodes. Bridges of moisture could short-circuit electrical connections and/or prevent the proper functioning of the device, particularly if the device has an electrical function, such as sensing via electrodes.

In some applications, a long-duration patch may experience excessive forces due to acute (quick and/or rapid) or chronic (slow and/or prolonged) contraction, stretching, or torsion. In such applications, the hinge points between a floating rigid section and flexible adhered sections may be modified in order to align with and counteract or mitigate the predominant direction of the force acting on the patch. In some device situations or configurations, the strength and direction of the acute or chronic force may be so strong that the forces imparted on the device adhesive surfaces or components may be distributed differently in addition to or as an alternative to the hinge described above.

Further, the device construction can be made in such a way that the housing is fashioned so that the axes of the housing are structured and placed along or against the direction of various forces, possibly during certain states, such as sleeping, so that the device itself can help counteract these forces and improve long-term adhesion.

Advantageously, the patch described herein can provide long-term adhesion to the skin. Having the various flexible portions and/or hinged portions can compensate for stressed caused as the skin stretches or bends, while allowing the rigid portion to float about the skin. As a result, the devices described herein can adhere to the skin substantially continuously for more than 24 hours, such as greater than 3 days, for example, greater than 7 days, greater than 14 days, or greater than 21 days.

Another mechanism for adhering a patch to the skin long-term is described with respect to FIGS. 7-10. As shown in the embodiments of FIGS. 7-10, one or more parts of the patch are used in a temporary fashion in order to improve adhesion. The adhesive used in the embodiments described below can include a hydrocolloid or a pressure-sensitive adhesive, such as polyacrylate, polyisobutylenes, or polysiloxane.

In one embodiment, shown in FIGS. 7A and 7B, the patch 700 can be surrounded with an adhesive 760 having multiple covers 701, 703, 705 thereon that can be peeled away in a sequence to expose strips of adhesive 760 underneath. The covers 701, 703, 705 can be concentric with one another and be configured to be pulled off separately and sequentially starting from the inside of the patch 700. Each additional exposed area of adhesive 760 can increase the adhesion life of the patch 700. Although only three covers are shown in FIG. 7A, other numbers, such as 2, 4, 5, or more are possible. Further, each electrode 124, 126 of the patch 700 can include a barrier 714, 716 to protect the electrodes 124, 126 from shortage.

In another embodiment, shown in FIGS. 8A and 8B, each electrode 124, 126 can be surrounded by a patch of adhesive 864, 866. Accordingly, a set of covers 801, 803, 805, 807 can be positioned sequentially around each of the electrodes 124, 126 over the adhesive 864, 866. The covers 801, 803, 805, 807 can be concentric with one another and be configured to be pulled off sequentially starting from the inside. Each additional exposed strip of adhesive 864, 866 can increase the adhesion life of the patch 100. Although only four covers are shown in FIG. 8A, other numbers, such as 2, 3, 5, or more are possible. Further, each electrode 124, 126 of the patch 800 can include a barrier 814, 816 to protect from shortage.

Referring to FIGS. 9A-9B, in other embodiments, shells or layers 901, 902, 903 can extend over all or a portion of

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the patch 900. Each layer 901, 902, 903 can include a strip of adhesive 962 on the bottom surface and an adhesion guard 982 protecting the adhesive. As shown in FIG. 913, as the patch 900 is worn over a period of time, the layers 901, 902, 903 can be sequentially removed. As a new layer is exposed, the adhesive guard 982 of that layer can be peeled away such that the adhesive 962 of the new layer can be used to adhere the patch 900 to the skin. In a similar embodiment, referring to FIGS. 10A-10B, each of the layers 1001, 1002, 1003 can include multiple portions of adhesive to help adhere the layer to both the skin and the patch itself. As with the embodiments of FIGS. 7-8, the number of layers in the embodiments of FIGS. 9 and 10 can vary. For example, there can be 2, 3, 4, or 5 or more layers.

In some embodiments, the layers or covers of the embodiments described herein can be added to the device over time to improve adhesion. Further, the multiple layers or covers of the embodiments described herein can be partially overlapped. Further, in some embodiments, the strips of adhesive can be overlapped.

Advantageously, the use of multiple covers or layers can assist in the adhesive performance of a base or core device because the added surface area or adhesive force of the combined outer layer aids in preventing layer pull away and/or may act to spread forces being experienced away from the core device by spreading those forces over a larger area.

Referring to FIGS. 11 and 12, an open cell structured support 1330 or porous foam can be used to support a more rigid or less flexible portion 1302 of the patch 1300. As shown in FIG. 11, the open cell structured support 1330 can fully fill an area below the rigid portion 1302. Alternatively, as shown in FIG. 12, the open cell structured support 1330 can be an annular shape or have some other configuration that includes spaces between adjacent portions of the support. The open cell structured support 1302 may be attached to both the skin and to the rigid portion, to only the rigid portion, or to only the skin. Because of the open cell structure of the support, the flexible movement of the skin can be absorbed by the structure entirely or partially such that the rigid portion does not impact or has a reduced impact on the ability of the device to accommodate movement and remain affixed. In addition, the open cell support may have a thickness selected to enhance patient comfort so that the more rigid portion of a device does not push against the skin. In one aspect, the open cell structure is a biocompatible foam material. In another aspect, the open cell material is positioned between an electronics module on the device and the skin when worn by a patient. The open cell support can advantageously absorb fluids to keep the electrodes from shorting.

Referring to FIG. 13, the patch can have a shell design. Adhesive can be placed on the perimeter edge of the bottom ring. The circuit board and electrode unit can be dropped into the bottom ring, and a shell can be dropped on top of the circuit board and electrode. The perimeter adhesive can create a watertight chamber therein.

The shape of a particular electronic device embodiment may vary. The shape, footprint, perimeter or boundary of the device may be a circle or circular (see FIG. 13A), an oval (see FIG. 1A, 2A), a triangle or generally triangular (see FIG. 1F) or a compound curve. Examples of a device embodiments having a compound curve shape are shown in FIGS. 2B, 2B, 3, 6A, 7A, and 8A. In some embodiments, the compound curve includes one or more concave curves and one or more convex curves. FIG. 3 illustrates a device having a convex surface along the top (where reference 102

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indicates), a concave surface along the bottom and convex shaped edges around the electrodes **124, 126**. FIGS. 2B and 2C illustrate a device embodiment having a convex shape on either side of the electronics **108** and around the electrodes **124, 126**. The convex shapes are separated by a concave portion. The concave portion is between the convex portion on the electronics and the convex portion on the electrodes. In some embodiments, the concave portion corresponds at least partially with a hinge, hinge region or area of reduced.

While described in the context of a heart monitor, the device adhesion improvements described herein are not so limited. The improvement described in this application may be applied to any of a wide variety of conventional physiological data monitoring, recording and/or transmitting devices. The improved adhesion design features may also be applied to conventional devices useful in the electronically controlled and/or time released delivery of pharmacological agents or blood testing, such as glucose monitors or other blood testing devices. As such, the description, characteristics and functionality of the components described herein may be modified as needed to include the specific components of a particular application such as electronics, antenna, power supplies or charging connections, data ports or connections for down loading or off loading information from the device, adding or offloading fluids from the device, monitoring or sensing elements such as electrodes, probes or sensors or any other component or components needed in the device specific function. In addition or alternatively, devices described herein may be used to detect, record, or transmit signals or information related to signals generated by a body including but not limited to one or more of EKG, EEG, and/or EMG.

What is claimed is:

1. An electronic device for long-term adhesion to a user, the device comprising:
a housing comprising a physiologic data collection circuit;

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an electrode-supporting section comprising a first substrate layer, a second substrate layer, and a lower adhesive layer positioned on a bottom surface, the lower adhesive layer providing adhesion to the skin of the user;

an electrode positioned on the bottom surface of the electrode-supporting section, the electrode electrically connected to the physiologic data collection circuit; and wherein the first substrate layer is positioned over the electrode and extends horizontally away from the housing beyond a boundary of the electrode; and wherein the second substrate layer is positioned over the first substrate layer and extends horizontally beyond a boundary of the first substrate layer.

2. The electronic device of claim 1, wherein the electrode supporting section further comprises a third substrate layer adhered to the first substrate layer.

3. The electronic device of claim 1, further comprising an upper adhesive layer positioned on the underside of the first substrate layer.

4. The electronic device of claim 1, wherein the lower adhesive layer extends at least partially below the housing.

5. The electronic device of claim 1, further comprising a flap extending beneath the housing.

6. The electronic device of claim 1, wherein the housing is rigid.

7. The electronic device of claim 1, wherein the housing is configured to remain connected to the electrode-supporting section when the housing is tilted at an angle relative the lower adhesive layer in response to movement of the user.

8. The electronic device of claim 1, further comprising a hinge portion adjacent the housing.

9. The electronic device of claim 1, wherein the lower adhesive layer comprises a hydrocolloid adhesive.

10. The electronic device of claim 1, wherein the physiologic data collection circuit is configured to collect cardiac rhythm data from the user.

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